Digital Interoperability

DPYD Clinical Pathway Analysis v0.9

NHS England and NHS Improvement

Contents

Control sheet

Version	Date	Modifiers	Updates
0.1	03/22	Adam L	Initial structure of document proposed and developed. Provisional datasets added.
0.2	03/22	Adam L	Datasets updated and comments added. Appendix updated. Use cases added and updated.
0.3	03/22	Adam L	Methods added.
0.4	04/22	Adam L	Methods updated.
0.5	13/04	Adam L	Use cases and clinical scenarios added for SW.
0.6	09/05	Adam L	Minimum data sets updated. Pain Points Test Order Forms
0.7	10/05	Adam L	Pain Points updated Test Order Forms updated
0.8	11/05	Adam L	Touchpoints amended Personas updated
0.9	12/05	Adam L	Pain points diagram added. Personas completed. Lesson learnt added.
0.9	13/05	Adam L	Diagrams updated.

Background

Currently, the GMS consists of seven GLH regions for NON-WGS genomic testing and one supplier for WGS. Across these regions, suppliers and primary/secondary/tertiary care settings, a vast range of systems are utilised to process genomic test orders. The disparity between these systems has created an inability to digitally interoperate. Inefficient, manual processes such as the distribution of hand written TOF and their transcription into the range systems have been established to bridge these gaps.

For the NHS England digital interoperability project, NHS England aims to deliver the ability to share genomic data across currently disparate systems. Within the scope of this work, NHS England is defining genomic information and data standards aligned with clinical, commissioning and patient needs to support the sharing of genomic tests requests and results across care settings and organisational boundaries.

The Test Directory is a centralised document which lists every clinical pathway available for request within the GMS. Due to the significant volume of clinical pathways, consultation with lead stakeholders confirmed a minimum set of clinical pathways which provide a broad and almost complete representation of the collective. Process elicitation and analysis will be completed and documented for each of these pathways, to understand the 'current state'. This will record; process models, use cases and pain points.

Genomic pathway use case matrix

For the chosen pathways, a matrix was constructed to provide an early, high level overview of each pathway and their properties. This enabled a steering group consisting of key stakeholders to review the coverage of chosen pathways against the wider set and decide upon the priority of analysis. DPYD was confirmed as the first to be completed. **Diagram 1A** shows the matrix for DPYD.

The 'Key data' aspect of **Diagram 1A** for each clinical pathway shows the specific test codes within scope and scientific/clinical properties. 'Service checkpoints' shares a high-level roadmap of the key touch points when ordering a genomic test from a given clinical pathway.

Diagram 1A - Genomic pathway DPYD use case matrix

Genomic pathway use cases matrix V1.0

Use cases	Key data								Service checkpoints																					
	A	B	C	D	E	F	G	H	I		J		K		L		M	N	O		P		Q		R		S	T	U	
	T.D test ids	Test method	Volume (% of tbc)	Complex Referral Structure RD terminology.	Test Procedure Oncology	Urgency	Type	Diagnosis/Treatment	RoD/Consent		Pedigree capture (RD)		Test order capture		Specimen		Sent to	DNA prep	Sample		Sequencing		Variant identification		Interp & results		Genomic MDT	Clinical reporting	MDT	
															Collection				Routed to											
									For tests	For research	Primary Care	Secondary Care	Primary Care	Secondary Care	Blood	Other tissue	GLH	GLH	GLH	Plating hub	GLH	Illumina	GLH	GEL	GLH	N/A	GTAB/GRDAB	GLH	GTAB/GRDAB MDT	Clinical MDT
Urgent/Non-urgent solid tumour cancer treatment pathway *(DPYD - Project Driven Pathway)*	M*	Hotspot	Unknown	Sing	S	Varied	Ph	Tr	Y		N/A	N/A		Y	Y		Y	Y	Y		Y		Y		Y			Y	N/A	Y

Terminology

Acronyms are heavily utilised throughout the NHS and therefore this document. **Table 1A** shows the meaning of each acronym used within this document. Whilst being generally applicable to the NHS, they were collected from a GMS perspective which may present some inconsistencies to the wider healthcare space.

Table 1A - Terminology

Acronym	Meaning
GMS	Genomic Medicine Service
PoC	Proof of Concept
TOF	Test Order Form
GLH	Genomics Laboratory Hub
C&S	Central and South GLH
Ea	East GLH
NE&Y	North East and Yorkshire GLH
NT	North Thames GLH
NW	North West GLH
SE	South East GLH
SW	South West GLH
WGS	Whole Genome Sequence
NON-WGS	Non Whole Genome Sequence
DPYD	Dihydropyrimidine Dehydrogenase - Protein coding gene
MDT	Multi-disciplinary Team
HCP	Healthcare Professional
CR	Clinical Report
OOS	Out of Scope
TD	Test Directory
SME	Subject Matter Expert
EHR	Electronic Health Record

DPYD genomic testing introduction

Ref: Cancer Research UK - DPD-Deficiency

DPD deficiency

Having a deficiency in the DPD enzyme could make the side effects of certain chemotherapy drugs worse. For some people, these side effects can be life threatening. This group of drugs are called fluoropyrimidines. Examples include 5-fluorouracil (5FU), capecitabine and tegafur.

What is DPD deficiency?

DPD stands for dihydropyrimidine dehydrogenase. It is an enzyme made by the liver that helps our body break down thymine and uracil. Thymine and uracil make up part of the structure of our genes. Genes are coded messages that tell cells how to behave. Uracil is also an important part of the drugs 5FU and capecitabine.

DPD deficiency happens when we have low or no levels of the DPD enzyme. The cause of this is usually changes (mutations) in the DPYD gene.

DPD deficiency and the side effects of capecitabine, 5FU and tegafur

The DPD enzyme helps our body to break down 5FU, capecitabine (also known as Xeloda) and tegafur (also known as tegafur-uracil and UFT). 5FU and capecitabine are two common chemotherapy drugs. They are used as a treatment for a number of different cancers, including:

- breast
- bowel
- head and neck
- stomach
- back passage (anus)
- bile duct
- pancreas
- neuroendocrine tumours or neoplasms

Without enough of the DPD enzyme, these chemotherapy drugs build up in our body and cause more severe side effects than usual. In some situations, these side effects can be life threatening.

Analysis approach

DPYD was the initial pathway to be analysed with prioritisation of subsequent pathways to be confirmed by the project steering board.

Diagram 2A shows a high level view of the analysis approach applied to the DPYD clinical pathway.

The following information sources were available:

1. Documentation (Public domain and internal).
2. Simultaneous Projects - Current projects which have relevant DPYD or genomic test ordering exposure.
3. Pathway Experts (SME) - Healthcare professionals working close to DPYD testing.

The first stage of this approach was as follows:

1. Gather available artefacts from the public domain (TOF/User guides) to review and analyse.
2. Request artefacts which are not available (Internal Documentation) to review and analyse.

Artefacts available in the public domain consisted of test order forms, user guides and information documentation. These were often sourced on the public GLH websites. Internal documentation was obtained by reaching out to healthcare professionals working close to DPYD or those who are engaged in current projects which have relevant DPYD or genomic test ordering exposure.

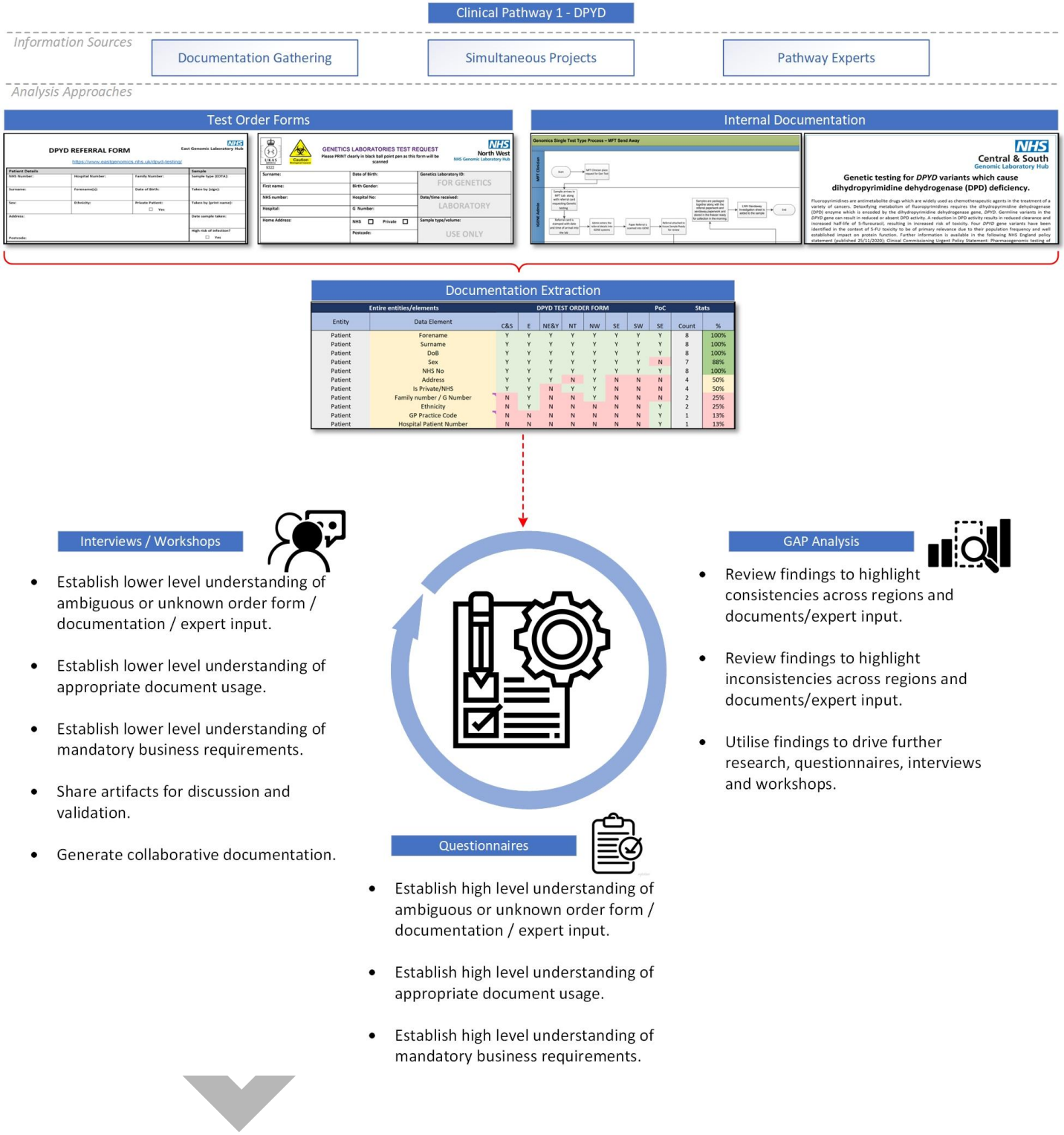
The second stage of this approach was as follows:

1. Available and provided artefacts were analysed.
2. Questionnaires, interviews and workshops were constructed and executed

As an understanding of the DPYD test ordering space was established, questionnaires, interviews and workshops were actioned to further validate findings and probe areas not addressed within available documentation. These elicitation techniques were applied as required, interchanging where needed without a linear expectation.

Questionnaires were utilised to clarify simple queries which arose from the prior documentation analysis. Interviews and workshops were utilised where deeper questioning was required for a more complex understanding. Interviews and workshops were also more supportive of collaborative working, providing extra value when reviewing documentation.

Diagram 2A - Clinical pathway analysis



Methods

Table 2A breaks down the proposed elicitation methods utilised, to a high level overview of the approaches and sessions which have taken place, with whom and to what outcome.

Table 2A - Methods utilised to elicit DPYD information

Method and focus	Stakeholders	Approach / Outcome
Documentation Review/Analysis **GAP Analysis** DPYD test order forms / user guides	None	**Review/Analysis of utilised DPYD test order forms and user guides.** 1. DPYD test order forms and user guides were obtained from GLH websites. 2. Datasets were extracted from test order forms. 3. GAP analysis applied to highlight consistencies and gaps across GLHs.
Questionnaires DPYD TOF	GLH Leads	**Questionnaires for initial TOF queries.** 1. Questionnaires were constructed to address short, initial TOF queries.
Workshops **Interviews** **Document Review/Analysis** **Questionnaires** DPYD TOF/user guides/business processes/process maps	NW Pharmacy Lead. NW DPYD Project Lead. NW DPYD Project BA. SE GLH Lead.	**Understanding of currently utilised DPYD test order forms / user guides and general processes established.** **Analysis of process maps provided by the North West DPYD project.** 1. DPYD test order forms and user guides were obtained from GLH websites. 2. Clarification sought from key stakeholders where aspects of documentation were unclear or ambiguous. 3. DPYD test ordering processes were established. 4. Available process maps obtained from the North West DPYD project. 5. Clarification sought via questionnaires and workshops on unclear or ambiguous aspects of the NW process maps.
Workshop DPYD process and data flows	East Clinical Scientist East GLH Lead	**Workshop with SMEs to confirm test ordering process and data flows.** 1. Workshop was facilitated with a clinical scientist and GLH Lead to determine DPYD process and data flows.
Document Review/Analysis **GAP Analysis** SE DPYD PoC project documentation	SE GLH Lead.	**Review/Analysis of datasets from the South East interoperability PoC project.** 1. Datasets utilised for the South East interoperability PoC project were included alongside the DPYD test order form datasets as part of the GAP analysis.
Document Review/Analysis NT reporting project documentation.	NT Project Manager	**Analysis of discovery documentation from the North Thames reporting project.** 1. Discovery documentation linked to reporting from the North Thames project was reviewed to identify generic test order reporting processes and potential datasets along with their FHIR mappings.
Document Review/Analysis **Workshops** Pathology standards	East Clinical Scientist NW Pharmacy Lead	**Analysis of pathology standard documentation.** 1. Potentially applicable test order data elements were extracted from the pathology standard. 2. Relevance of data elements confirmed with clinicians.
Workshops Generic and DPYD process flows reviewed.	SE GLH Lead	**Workshops with SME to confirm test ordering process flows.** 1. Workshops were facilitated with SME to determine current process flows for generic, genomic test ordering.

		2. Process flows utilised as a baseline, in conjunction with further SME input to create DPYD specific process flows.

TOF and SE PoC data analysis and findings

As part of the initial analysis, DPYD TOF were collated and analysed with the following test order forms considered (**see appendix*):

1. Central and South DPYD (C&S)
2. East DPYD (Ea)
3. North East and Yorkshire DPYD (NE&Y)
4. North Thames DPYD (NT)
5. North West generic (NW)
6. South East DPYD (SE)
7. South West DPYD (SW)

Analysis applied to the DPYD TOF:

1. TOF were obtained from GLH websites.
2. TOF were reviewed to understand context and content.
3. Meaning and purpose of ambiguous data elements clarified by research or pathway experts via questionnaires/workshops.
4. Applicable data elements were extracted from the TOF.
5. All TOF data elements were collated alongside SE PoC data elements.
6. Occurrence percentages were calculated.
7. Data elements were ordered by prevalence.

Analysis of the DPYD TOF confirmed conomanalities and differences in approaches to collecting data and which data was collected across the regions covered.

Data collection approaches included checkboxes, free text boxes and applying printed stickers over TOF sections.

The data added by the referring clinician on each TOF varied significantly with common fields such as ‘Patient Name’ evident on all and more unique fields such as ‘Ethnicity’ evident on one. Occurrence figures have been captured on **Table 3A/B**.

The South East Interoperability Proof of Concept project provided the data set they required to create a test order. As these were relevant to the datasets collated from the TOF, requirements from this PoC were also brought into the analysis shown by **Table 3A/B**.

From the TOF analysis and subsequent workshops, it found that test order forms are completed in the following ways:

1. Original TOF is printed and completed by hand.
2. Original TOF is printed along with a patient/request sticker which is placed over the form fields before clinician signing.
3. Original TOF is completed electronically as a PDF using interactive dropdowns before being printed.
4. A bespoke, completed request form is printed by the healthcare system used by a requesting organisation.

Workshops also confirmed that some regions use a ‘catch all’ TOF which covers a range of genomic tests, and will therefore have elements irrelevant to DPYD. Requesting clinicians use tacit knowledge to complete only applicable aspects of a TOF knowing which relate to the test request they are making. Many TOF are also out of date, containing elements which are to no detriment, incorrect or no longer relevant.

It also became apparent that labs could receive TOF generated by systems from requesting organisations which are not available in the public domain. As these particular forms have evolved over time, they present the required information and are computer printed, therefore remove any legibility concerns. The minor problem utilisation of a bespoke order form presents is a laboratory is expected to receive a range of form types for the same test. This requires users to be aware of the variety and potential challenges it presents.

Where a TOF is incomplete, incorrect or illegible, if possible, the tests will still be progressed up to the point of clinical reporting, thus providing time to chase the incomplete details without slowing down service delivery. There are some elements which, if erroneous, result in a complete stop to processing, such as not being able to match a sample/specimen to a TOF. Some data elements on the TOF are not required to complete a genomic test within the laboratory space, however, like reporting, they are mandatory for billing to take place once a test is complete. This applied in particular to test identification codes being declared, with lower level IDs being irrelevant for the DPYD test, but critical for billing. In some forms, this is not captured as an ID but as a type of cancer the test is being applied to.

Whilst the TOF analysis provided a broad awareness of the DPYD space and a platform upon which to build valuable discussion, the statistical outcomes when compared to findings from interviews and workshops proved to be of no value. Higher occurrences of data elements across TOF did not directly correlate to an increased requirement, as lower occurrences did not directly correlate to a lesser requirement. Direct discussions with key stakeholders confirmed that business rules which confirm the validity of a TOF, vary slightly

across regions and could not be determined by review of TOF in isolation. From the GLH websites reviewed, only one user guide was found which addressed the business requirements for a successful DPYD TOF and this considered just the initial request aspect of the test, omitting the clinical reporting requirements.

Table 3A - Summary of data elements evident on TOF and SE PoC

Patient										
TOF Entities/elements	**DPYD Test Order Form**							**PoC**	**Stats**	
Data Element	**C&S**	**Ea**	**NE&Y**	**NT**	**NW**	**SE**	**SW**	**SE**	**Count**	**%**
Forename	Y	Y	Y	Y	Y	Y	Y	Y	8	100%
Surname	Y	Y	Y	Y	Y	Y	Y	Y	8	100%
DoB	Y	Y	Y	Y	Y	Y	Y	Y	8	100%
Sex	Y	Y	Y	Y	Y	Y	Y	N	7	88%
NHS No	Y	Y	Y	Y	Y	Y	Y	Y	8	100%
Address	Y	Y	Y	N	Y	N	N	N	4	50%
Is Private/NHS	Y	Y	N	Y	Y	N	N	N	4	50%
Family number / G Number	N	Y	N	N	Y	N	N	N	2	25%
Ethnicity	N	Y	N	N	N	N	N	Y	2	25%
GP Practice Code	N	N	N	N	N	N	N	Y	1	13%
Hospital Patient Number	N	N	N	N	N	N	N	Y	1	13%
Referring Hospital										
Reg No	Y	Y	Y	Y	Y	Y	N	N	6	75%
Name	N	Y	Y	N	N	N	Y	Y	4	50%
Address	N	Y	N	N	N	N	N	N	1	13%
Postcode	N	Y	N	N	N	N	N	N	1	13%
ODS Code	N	N	N	N	N	N	N	Y	1	13%
Order Ref	N	N	N	N	N	N	N	Y	1	13%
Referring Clinician										
Names	Y	Y	Y	Y	Y	Y	Y	Y	8	100%
Email	Y	Y	Y	Y	Y	Y	Y	Y	8	100%
Telephone	Y	Y	N	Y	Y	Y	Y	Y	7	88%
Ward / Clinic / Dep / Surg	N	N	Y	N	Y	N	Y	N	3	38%
Signature	N	N	N	N	Y	N	N	N	1	13%
Fax	N	N	N	N	Y	N	N	N	1	13%
Speciality	N	Y	N	N	N	N	N	N	1	13%
Reporting To										
Email	Y	Y	Y	Y	N	N	Y	N	5	63%
Hospital Name	N	N	N	Y	N	N	Y	N	2	25%
Department	N	N	N	Y	N	N	Y	N	2	25%
Address	N	N	N	Y	N	N	Y	N	2	25%
Test Request										
Clinical summary / Ref reason	Y	Y	Y	N	Y	Y	Y	N	6	75%
Test Directory code	Y	Y	Y	N	Y	Y	Y	Y	7	88%
Tumour Type/Diag/Disease stage	Y	N	Y	Y	Y	N	N	N	4	50%
T.Type (DNA/RNA NGS PNL/FISH)	Y	N	N	Y	Y	N	N	Y	4	50%
Is urgent	N	N	Y	N	N	N	N	N	1	13%
Contact for urgent results	N	N	Y	N	N	N	N	N	1	13%
Partner DOB	N	N	N	N	Y	N	N	N	1	13%
Gravida	N	N	N	N	Y	N	N	N	1	13%
Para	N	N	N	N	Y	N	N	N	1	13%
LMP	N	N	N	N	Y	N	N	N	1	13%
OLN/RLN Originating/Ref Lab ID	N	N	N	N	N	Y	N	N	1	13%
Date sample sent	Y	N	N	N	N	N	N	N	1	13%

Table 3B - Summary of data elements evident on TOF and SE PoC

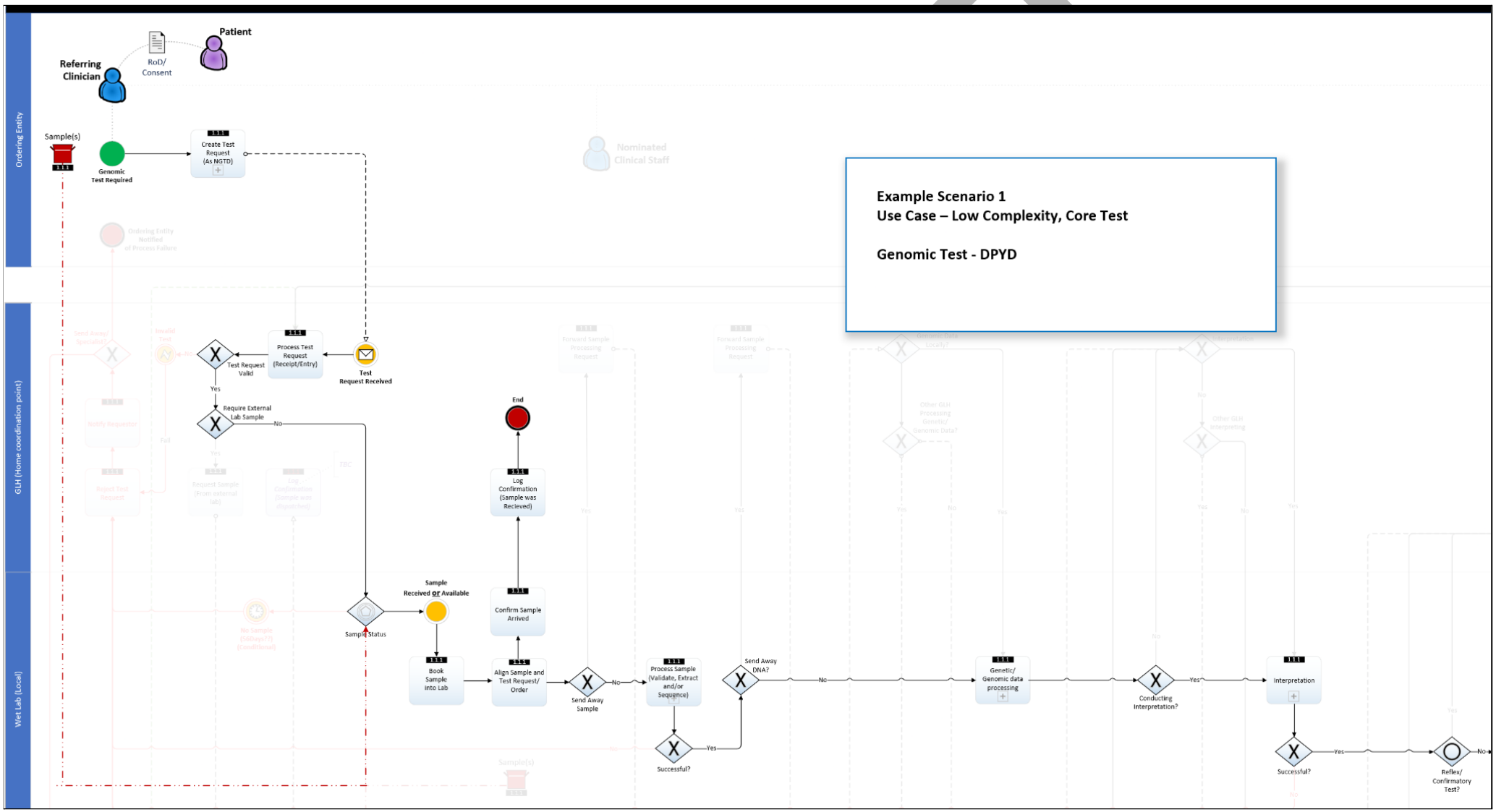
Specimen										
TOF Entities/elements	**DPYD Test Order Form**							**PoC**	**Stats**	
Data Element	**C&S**	**Ea**	**NE&Y**	**NT**	**NW**	**SE**	**SW**	**SE**	**Count**	**%**
is Pre/Post Fluorouracil (5FU)	N	Y	N	N	N	Y	N	Y	3	38%
Sample ID	N	N	N	N	N	N	Y	Y	2	25%
Tissue Type	N	N	N	Y	Y	N	N	N	2	25%
Taken by (sign)	N	Y	N	N	Y	N	N	N	2	25%
Pathology block number	Y	N	N	N	N	N	N	N	1	13%
Taken by (print)	N	Y	N	N	N	N	N	N	1	13%
Neoplastic nuclei	Y	N	N	N	N	N	N	N	1	13%
Cellularity	Y	N	N	N	N	N	N	N	1	13%
Necrotic	N	N	N	Y	N	N	N	N	1	13%
High melanin content	N	N	N	Y	N	N	N	N	1	13%
High risk of infection	N	Y	N	N	N	N	N	N	1	13%
Viral Hep B	N	N	N	N	Y	N	N	N	1	13%
Other HR infection	N	N	N	N	Y	N	N	N	1	13%
Other HR infection name	N	N	N	N	Y	N	N	N	1	13%
Consent to store	N	N	N	N	Y	N	N	N	1	13%
Volume	N	N	N	N	N	N	N	Y	1	13%
Courier Method	N	N	N	N	N	N	N	Y	1	13%
Temperature Control	N	N	N	N	N	N	N	Y	1	13%
Results*										
Lab request ref	N	N	N	N	N	N	N	Y	1	13%
TestType(D/RNA NGSPANEL/FISH)	N	N	N	N	N	N	N	Y	1	13%
Lab Sample Type	N	N	N	N	N	N	N	Y	1	13%
Results Test	N	N	N	N	N	N	N	Y	1	13%
Methodology	N	N	N	N	N	N	N	Y	1	13%
Results Document Ref	N	N	N	N	N	N	N	Y	1	13%
Variant Level Results	N	N	N	N	N	N	N	Y	1	13%
Hospital Order Ref	N	N	N	N	N	N	N	Y	1	13%
NHS Number	N	N	N	N	N	N	N	Y	1	13%
Lab Patient Number	N	N	N	N	N	N	N	Y	1	13%
Hospital Sample ID	N	N	N	N	N	N	N	Y	1	13%

**No data elements regarding results were evident on any of the TOF reviewed. The datasets considered for this aspect of the test order process were derived from documentation provided by the South East PoC.*

Generic DPYD clinical pathway process flow

Michael to add intro and updated diagram. Caveat with at time of publication, the process map is going through validation.

Diagram 3A - DPYD clinical pathway process flow



DPYD clinical pathway use case steps and clinical scenarios

Table 4A,B and **C** show the use case steps and clinical scenarios for DPYD in the North West, South West and North East and Yorkshire GLH regions.

Each table consists of current state DPYD test ordering :

1. Use case steps
2. Clinical scenarios
3. FHIR resource mapping

The use case steps are a list of actions or event steps defining the interactions between individuals, specific roles and or systems to achieve the ordering of a DPYD test. The clinical scenarios add in specifics, adding in anonymised names of individuals but using real organisation names relating to the region considered.

FHIR resource mapping breaks down the overarching messaging elements into known FHIR resources.

Table 4A

North West - DPYD test ordering from a Pharmacy Lead Perspective	
Use case steps	
1. Cancer patient referred to oncology. 2. Cancer patient has a DPYD test order form completed by an oncologist. 3. Blood specimen collected at oncology outpatients. 4. DPYD test order form and specimen physically sent to the home laboratory. 5. DPYD test order form and specimen are received at the home laboratory. 6. Test order is entered into LIMS and DNA extracted from blood specimen. 7. DPYD test request and DNA extraction are physically forwarded to a 'send away' laboratory. 8. DPYD test request and DNA extraction are received by 'send away' laboratory and logged into LIMS. 9. DPYD sample is processed, generating a result. 10. Interpretation applied to the result, producing a clinical report. 11. Clinical report sent to the laboratory at oncology. 12. Clinical report is received at the oncology laboratory and manually entered into the EHR system. 13. Pharmacy access the clinical report via the EHR system. 14. Pharmacy prescribes medication as per clinical report.	
Clinical scenario	
Michael Jones, a 50 year old man, attends an appointment at an oncology outpatient clinic in The Christie to treat his pancreatic cancer. The oncologist, Dr Lucy Hale, gives Michael a blood test form for DPYD and asks him to attend The Christie's clinic. Michael attends the appointment where a blood specimen is taken by Mary Lane and physically sent, along with the test order form to the Manchester laboratory. The test order form and blood specimen details are logged into the Manchester LIMS and DNA is extracted from the specimen. The test request and DNA extraction are physically sent to Liverpool Women's laboratory and logged into their LIMS. The DNA extraction is processed, generating a result which is analysed and its interpretation is used to create a clinical report. This clinical report is sent to The Christie laboratory where it is manually entered into The Christie's EHR system. The pharmacy obtain Michael's prescription titration from the EHR system.	
FHIR resource mapping	
Named participants	• Patient: Michael Jones – FHIR Resource: Patient • Requesting HCP: Dr Lucy Hale – FHIR Resource: Practitioner • Specimen Collecting HCP: Mary Lane – FHIR Resource: Practitioner
Named Organisations	• Requesting Organisation: The Christie (Oncology) – FHIR Resource: Organisation • Specimen Collecting Organisation: The Christie (Oncology) – FHIR Resource: Organisation • Performing Organisation: Manchester Royal Infirmary (Blood Sciences) – FHIR Resource: Organisation • Send Away Performing Organisation: Liverpool Women's (Blood Sciences) – FHIR Resource: Organisation
Condition	• Pancreatic cancer – FHIR Resource: Condition
Required Tests	• DPYD Hotspot – FHIR Resource: ServiceRequest

Specimen(s)	• Blood – FHIR Resource: Specimen
Test Results	• FHIR Resource: Observation
Test Report	• FHIR Resource: DiagnosticReport

Table 4B

North East and Yorkshire - DPYD (WGS) test ordering - Paediatric Oncologist perspective.	
Use case steps	
1. Suspected paediatric cancer patient is referred to 'Tertiary Care'. 2. Pre-diagnosis phase initiates with baseline blood and tissue samples captured at 'Paediatric Oncology Outpatients' for assessment. 3. Following a positive diagnosis, patients have a WGS test order form completed by their Oncologist. 4. WGS test order form and blood and tissue samples previously collected are physically sent to the local laboratory. 5. WGS test order form and blood and tissue samples previously collected are received and logged at the local laboratory. *6. Internal laboratory procedure unknown by Paediatric Oncologist.* 7. Clinical report sent to originating Paediatric Oncologist (Physical in-tray or electronic mail). 8. A multi-disciplinary team (MDT) meets to review the report and agree on an approach. 9. A prescription is generated by a Paediatric Pharmacist and signed by a Paediatric Oncologist. 10. Treatment commences. **As the Paediatric Oncologists require further genomic testing beyond just DPYD, WGS is ordered to cover all.*	
Clinical scenario	
Patient Lily Marks, a 7 year old girl with suspected cancer, attends an appointment at Leeds Paediatric Oncology Outpatients. She has blood and tissue samples taken by HCP Paul Karr. Following a positive diagnosis, the Paediatric Oncologist, Dr Linda Lumb, completes a WGS test order form which includes a test for DPYD. The WGS test order form and previously collected blood and tissue samples are sent to the local laboratory. *Internal laboratory procedure unknown by Paediatric Oncologist.* Once the clinical report is ready, it is sent physically or digitally to the originating Paediatric Oncologist, Dr Linda Lumb. An MDT review the report and agree on an approach. The Paediatric Pharmacist, Dr Jenny Lane, generates the prescription which is then signed by the originating Paediatric Oncologist, Dr Linda Lumb. Once the prescription has been signed, patient Lily Marks begins treatment at Leeds Paediatric Oncology.	
FHIR resource mapping	
Named participants	• Patient: Lily Marks – FHIR Resource: Patient • Requesting HCP: Dr Linda Lumb – FHIR Resource: Practitioner • Specimen Collecting HCP: Paul Carr – FHIR Resource: Practitioner • Paediatric Pharmacist: Dr Jenny Lane – FHIR Resource: Practitioner
Named Organisations	• Requesting Organisation: Leeds Paediatric (Oncology) – FHIR Resource: Organisation • Specimen Collecting Organisation: Leeds Paediatric (Oncology) – FHIR Resource: Organisation • Performing Organisation: Local Laboratory – FHIR Resource: Organisation
Condition	• Cancer – FHIR Resource: Condition
Required Tests	• WGS Panel – FHIR Resource: ServiceRequest
Specimen(s)	• Blood – FHIR Resource: Specimen
Test Results	• FHIR Resource: Observation
Test Report	• FHIR Resource: DiagnosticReport

Table 4C

South West - DPYD test ordering sourced from GLH website	
Use case steps	
1. Cancer patient referred to secondary care. 2. Cancer patient has a DPYD test order form completed by an oncologist. 3. Blood specimen collected at secondary care. 4. DPYD test order form and specimen physically sent to the local laboratory and progressed to the genomics department. 5. Test order is booked into LIMS. 6. Label printed with patients name and sample number. 7. Sample is moved to the extraction laboratory where it is prepared for testing. 8. DNA is extracted. 9. DNA extraction is taken to pre-amplification and amplification laboratories where LAMP with melt curve analysis is applied. 10. Results are recorded. 11. Interpretation applied to the results, producing a clinical report. 12. Clinical report emailed to the trust NHS mailbox linked to the referring clinician. 13. Prescribing pharmacies access this mailbox. 14. The chemotherapy prescribing system has a DPD confirmation element which must be completed before the prescription can be given. 15. Using the clinical report, the cancer patient's prescription is titrated and made available at the pharmacy. **https://www.youtube.com/watch?v=opMSQcmzfbg*	
Clinical scenario	
Claire James, a 50 year old woman, attends an appointment at an oncology outpatient clinic in Bristol Haematological and Oncology Centre (BHOC) to treat her lung cancer. The oncologist, Dr Martin Lamb, gives Claire a blood test form for DPYD and asks her to attend BHOC phlebotomy clinic. Claire attends the phlebotomy appointment where a blood specimen is taken by Cain Milkey and physically sent, along with the test order form to the Severn Pathology Laboratory. The test order form and blood specimen details are booked into the Severn Genomics LIMS and a label is produced for the sample. Sample is moved to the extraction laboratory where it is prepared for testing by having the DNA extracted. The DNA sample is taken to pre-amplification and amplification laboratories where LAMP with melt curve analysis is applied. Interpretation is applied to the result, producing a clinical report. The clinical report is emailed to the trust NHS mailbox linked to the referring clinician. Prescribing pharmacies access this mailbox. The chemotherapy prescribing system has a DPD line which is checked for completion before the prescription can be processed. Using the clinical report, the cancer patient's prescription is titrated and made available at the pharmacy.	
FHIR resource mapping	
Named participants	• Patient: Claire James – FHIR Resource: Patient • Requesting HCP: Dr Martin Lamb – FHIR Resource: Practitioner • Specimen Collecting HCP: Cain Milkey – FHIR Resource: Practitioner
Named Organisations	• Requesting Organisation: The Christie (Oncology) – FHIR Resource: Organisation • Specimen Collecting Organisation: Bristol Haematological and Oncology Centre – FHIR Resource: Organisation • Performing Organisation: Severn Pathology (Genomics) Laboratory – FHIR Resource: Organisation
Condition	• Lung cancer – FHIR Resource: Condition
Required Tests	• DPYD Hotspot – FHIR Resource: ServiceRequest
Specimen(s)	• Blood – FHIR Resource: Specimen
Test Results	• FHIR Resource: Observation
Test Report	• FHIR Resource: DiagnosticReport

DPYD pathway touchpoint minimal requirements.

Throughout the DPYD clinical pathway process, there are minimal data requirements to successfully progress at each touch point. These requirements are obtained from a system agnostic perspective, understanding what would be the minimum requirement to proceed. **Diagram 4A** shows the process map touchpoints.

The scope of this project covers up to the test request and sample submission, then from the creation and distribution of the clinical report. Actions occurring within the laboratory space between these points are deemed out of scope.

Table 5A/B shows the minimum data requirements for the North West and East when requesting a DPYD genomic test. This is split by sample, referral form and clinical report.

Diagram 4A - High level DPYD pathway touch point process map

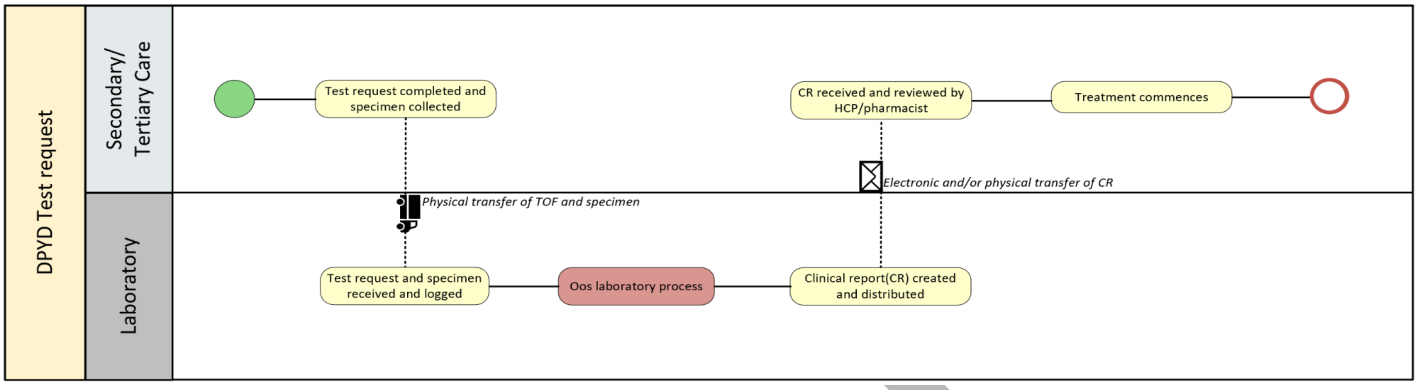


Table 5A - DPYD pathway touch point minimum requirements

DPYD pathway touchpoint minimum requirements - North West		
Ref	**Touchpoint**	**Minimum Attributes** [*All mandatory unless stated otherwise*]
1	Accept a test order and specimen/sample at the home lab.	**Sample** Patient first name Patient surname Patient dob NHS number* [*Any combination of the above to accurately match to a TOF*] High risk sample confirmation [*If applicable*] High risk sample reason [*If applicable*] **Referral Form** Patient first name Patient surname Patient dob [*Two of the above*] NHS number* [*If available*] Referral clinician name Patient hospital name Test requested Email address for report
Expectation of a match between sample and referral form to progress.		
1a	Internal lab activity (out of scope)	
2	Create and distribute the concluding report.	**Report** Reason for referral DPYD result Patient first name Patient surname

		Patient hospital reference number Email address for report Further interested parties email addresses for report copy [*If required*]

Table 5B - DPYD pathway touch point minimum requirements

DPYD Pathway Touchpoint Minimum Requirements - East		
Ref	**Touchpoint**	**Minimum Attributes** [*All mandatory unless stated otherwise*]
1	Accept a test order and specimen/sample at the home lab.	**Sample**
		Patient first name Patient surname Patient dob Address NHS number* [*Any combination of the above to accurately match to a TOF*]
		Referral Form
		Patient first name Patient surname Patient dob Patient Address [*Three of the above*] NHS number* [*If available*] Referral clinician name Patient hospital name Patient hospital number Test requested HL code Test requested LL code Central Email address for report Referrer sample ID Pre/Post chemotherapy
Expectation of a match between sample and referral form to progress.		
1a	Internal lab activity (out of scope)	
2	Create and distribute the concluding report.	**Report**
		Reason for referral DPYD result - Summary strapline - Result summary including genotype and actions - Technical details regarding testing methodology and guidance applied. ISO standards Patient first name Patient surname Patient hospital number NHS number* [*If available*] Patient hospital reference number Central email address for report Referrer sample ID HGVS recordings of changes.

**NHS Number is mandatory where available however not every patient will have an NHS number, for example; non-uk patients.*

Mapping of touchpoint requirements to known data elements and FHIR.

FHIR is a messaging standard currently used within the healthcare sector. The current minimum data requirements for DPYD test ordering have been mapped to current FHIR elements to understand what could be re-used and what may need to be additionally developed.

Following confirmation from by the North West and East GLHs **Table 6A** combines the required data elements confirmed by the North West and East GLHs, the properties associated with these

Table 6A - DPYD pathway touch points mapped to FHIR

DPYD Pathway touch points		
Requirement Attributes	**FHIR**	**Comments**
Named Participants		
Patient first name	FHIR	Referred patient's first name.
Patient surname	FHIR	Referred patient's last name.
Patient dob	FHIR	Referred patient's DoB.
Patient address	FHIR	Referred patient's address.
Patient NHS number	FHIR	Referred patient's NHS number.
Patient hospital name	FHIR	Name of the hospital with the referred patient.
Patient's ID at referring hospital	FHIR	ID of the patient at the referring hospital.
Referring clinician name	FHIR	Referring clinician's name.
Required Test		
Test ID	FHIR	Requested test code. This is the lowest level code referring to the specific test requested from the TD.
Test CID	FHIR	Requested test clinical indication code. Highest level code referring to the overarching test requested from the TD.
High risk sample	FHIR	Confirmation if the sample is high risk.
High risk sample reason	FHIR	If a sample is high risk, this confirms why.
Sample / Specimen		
Sample ID from referring lab	FHIR	ID recognised in the referring lab systems for a particular sample.
Pre/post chemo	FHIR	Confirmation if the sample is from a patient who is pre or post chemotherapy treatment.
Test Report		
Email address for report	FHIR	Email address for clinical report to be sent to.
Reason for referral	FHIR	Reason for the test request.
DPYD result summary	FHIR	High level strapline of the result outcome.
DPYD result genotypes and actions	FHIR	Resulting genotypes and following actions based on findings.
DPYD result methodology/guidance applied.	FHIR	Methodologies and guidance applied to completed tests and clinical report.
ISO standards	FHIR	ISO standards to be included on every clinical report.
HGVS recordings of changes	FHIR	Genomic standard nomenclature to represent findings.

Pain Points

Pain points are aspects of the current DPYD process which cause problems to the user, resulting in inefficiency and subsequent resource cost. **Diagram 5A** states the pain points elicited during workshop and interview sessions with laboratory leads, clinicians and clinical scientists.

The highest impacting pain points are related to the manual completion of TOF, in particular, when they are received incomplete, inaccurate, incorrect or illegible. Being unable to obtain sufficient information from a TOF results in either a delayed or completely stopped test request. These delays and stops can lead to a detriment in patient care. It has been confirmed that some laboratories receive a range of different TOF for the same DPYD test which will require further up front training of transcribers and increase the potential for transcription error due to extra considerations. As the forms are completed manually, there is also an ongoing need for paper, working printers and sometimes scanners.

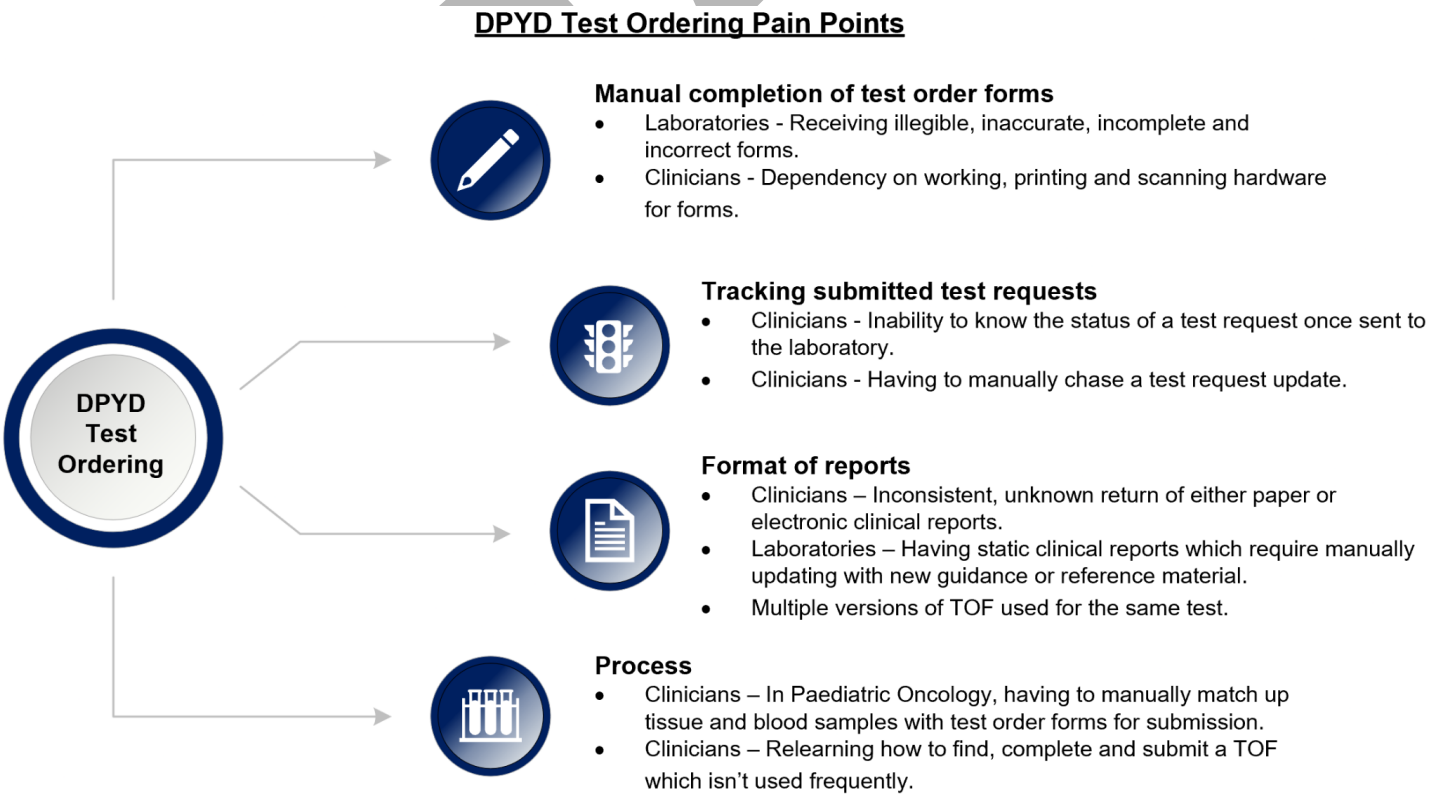
Clinicians who rarely order DPYD tests confirmed that locating and understanding the test request process/TOF, was inefficient and time consuming. It was suggested that the process is not easy to find and follow, particularly as it is mainly manual with minimal supporting validations.

Upon making DPYD test requests, test request statuses are currently unavailable within the regions where workshops were run. This results in clinicians not being aware of where their requests sit and if there are any concerns requiring their input to progress. To confirm where a test request is, difficult chaser emails and/or phone calls need to be made which consumes further resources.

One region shared that clinical reports may be returned in physical or electronic format, with no indication or consistency as to which. This approach reduces the effectiveness of a clinician being able to monitor their returned reports. The physical delivery of a clinical report in particular, poses audit trail concerns and has an increased risk of loss.

The final paint point, more applicable to paediatrics as they order WGS for DPYD, was the need to match both blood and tissue samples to each other and then to physical order forms. This approach is logistically difficult.

Diagram 5A - Pain points



Personas

Questionnaires, workshops and interviews which took place, involved key stakeholders within the DPYD ordering space.

The following stakeholders were engaged with to understand the DPYD process from different regional and role perspectives:

1. Clinical Scientist from the East GLH.
2. Pharmacy Lead from the NW GLH.
3. Paediatric Oncologist from the NE&Y GLH.

Diagrams 6A - 6C provide further detail on these SMEs, covering their background, general tasks, core needs, frustrations and systems used. Names have been anonymised.

Diagram 6A

<table>
<tr><th colspan="2">Tim Brown</th></tr>
<tr><td>  </td><td>Role: Clinical Scientist
Location: East GLH

Bio
Tim has been working within the East labs since 2004. He has extensive education with how the laboratories operate working with a range of technologies, methodologies and project requirements.</td></tr>
<tr><td colspan="2">Tasks
Oversees the genomic test referral processes.
Checks the suitability of requested tests.
Monitors resources.</td></tr>
<tr><td colspan="2">Core Needs
Complete and accurate test order referrals.
The ability to match test request order forms and samples.
Access to clinicians to confirm incomplete/inaccurate test requests.</td></tr>
<tr><td colspan="2">Fraustrations
Multiple types of forms are received by the labs.
If manually written, legibility of handwriting can be problematic.
Forms can be incorrectly completed.</td></tr>
<tr><td colspan="2">Systems Used
 
EPIC
 
SHIRE / GEMINI</td></tr>
</table>

Diagram 6B

Mark Phillips

Role: Paediatric Oncologist
Location: Leeds Children (LGI)

Bio

Mark Phillips has been a Paediatric Consultant for 14 years, specialising in Oncology. Along with direct care, he provides supportive care and guideline direction to ensure proper practice. His need for DPYD (WGS) testing is infrequent as targeted cancers are less common in children.

"As I don't often need to order a DPYD test, when I do, it's like starting from scratch trying to find and follow the process.
Given the need for other genomic tests to be completed, we order DPYD as part of a WGS request."

Tasks

- Order DPYD (WGS) test
- Receive DPYD (WGS) report / Attend MDT meeting to confirm approach
- Sign off prescriptions

Core Needs

- Simplistic, self evident test order procedure
- To know the status of a test order
- Clear and consistent clinical reports

Fraustrations

- Finding/re-learning the test order process due to infrequent use
- WGS test requests require the difficult alignment of both blood and tissue with the order form
- Uncertainty on test request statuses
- Dependency on working hardware (scanner/printer)
- Uncertain if a report may arrive electronically or on paper

Systems Used

EPR

TD Website

Email

Print/Scanning

Chemotherapy Prescription System

Diagram 6C

Jenny Jones

Bio

Jenny Jones is an independent prescriber who requests the DPYD tests and uses results to inform patients treatments. Jenny has exposure to the initial DPYD ordering process, then the prescribing process once a clinical report has been uploaded to the EHR at the Christie.

Role: Pharmacy Lead
Location: Christies (NW)

Tasks

- Operates requests the DPYD tests
- Utilises results to inform patients treatments
- Provides input as Pharmacy Lead for the NW GMSA

Fraustrations

- Alerts for allergies are added to certain results as a work around which is inaccurate.
- No awareness of test order statuses resulting in chasing.

Systems Used

Lessons Learnt

As the analysis completed for the DPYD clinical will be replicated for further pathways, lessons learnt have been documented in **Table7A** to centralise key findings and support the improvement of future approaches.

The lessons learnt are predominantly related to the following categories:

1. The dependency on supporting projects/stakeholders and their ability to respond in a timely manner with material to an expected level of detail.
2. The removal of assumptions when reviewing available documentation.

Table 7A - Lessons Learnt

Ref	Incident	Lesson Learnt	Action	Owner
1	TOF available on GLH website was not currently in use. This assumption resulted in a loss of resource preparing for sessions with incorrect documentation.	Applicably titled test order forms available online may not be what is currently used in practice.	Establish which test order form is being used upfront.	Adam Laurent
2	Supporting projects which DPYD analysis was partially dependent on took longer than planned to share documentation.	Supporting projects can encounter unavoidable delays which impact the sharing of key information.	Engage as early as possible and plan/prepare alternative sources of information.	Adam Laurent / Michael Price
3	Supporting projects which DPYD analysis was partially dependent on, provided information to a level lower than planned.	Supporting projects may share information which is not to the level expected.	Engage as early as possible and plan/prepare alternative sources of information. Discuss expectations upfront.	Adam Laurent / Michael Price
4	Supporting projects which DPYD analysis was partially dependent on, did not provide information as originally planned.	Supporting projects may not be able to share information which was originally planned.	Engage as early as possible and plan/prepare alternative sources of information. Discuss expectations upfront.	Adam Laurent / Michael Price
5	The utilisation of online information alone didn't provide clear enough information and understanding without being validated.	Online information sources are unlikely to be sufficient without SME input.	Despite having significant amounts of information available online, engage with SMEs earlier where possible.	Adam Laurent
6	Aspects of TOF which appeared to be critical, were confirmed to be redundant.	Clarify as many assumptions as possible via SME input.	Engage and confirm with SMEs as early and as frequently as possible.	Adam Laurent
7	Key stakeholders took longer than expected to confirm queries raised.	Supporting stakeholders may encounter unavoidable delays with responding to queries.	Engage as early as possible and plan/prepare alternative sources of confirmation.	Adam Laurent

Appendix

Genomic test order forms
Central and South GLH genomic test ordering form

Birmingham Women's and Children's Health Care NHS Trust Mindelsohn Way, Edgbaston, Birmingham B15 2TG	West Midlands Regional Genetics Laboratory Central and South Genomic Laboratory Hub **CANCER GENOMIC TEST REQUEST**	Tel: (0121) 335 8036 Fax: (0121) 335 8028 E-mail: bwc.genetics.lab@nhs.net https://bwc.nhs.uk/west-midlands-regional-genetics-laboratory

Patient Information:		
Surname:	**First name(s):**	
DoB:	**Sex:** Male / Female / Unknown	**Type:** NHS / Private
NHS No.:	**Hospital Reg. No.:**	
Address:		

Referrer Information:
Referring Clinician(s):
Address for reporting: Reports can only be emailed to a centralised administrative team; registration of an nhs.net account is required – contact laboratory for further information
Contact details: **Tel.:** **Email:**

Test Request: THIS FORM MUST NOT BE USED FOR WHOLE GENOME SEQUENCING TEST REQUEST	
Tumour type / organ of origin:	**Diagnosis:**
Reason for referral / Clinical summary (please include a copy of the pathology report):	
Test(s) required (please tick): please refer to https://www.england.nhs.uk/publication/national-genomic-test-directories/ **NHSE Test Directory code:** **Gene target(s):** **DNA NGS Panel** ☐ **RNA NGS Panel** ☐ **FISH (please specify probes)** ☐ _____	

Tissue Sample Details:			
Please tick appropriate box according to your local pathology assessment of the tissue sent for testing: **Neoplastic nuclei in marked H&E:** ☐ **<20%** ☐ **if > 20% please specify:**_____ **Cellularity:** ☐ **High** ☐ **Intermediate** ☐ **Low** ☐ **Very Low**			
Date biopsy/resection taken:	**Pathology Block No.:**	**Date sample sent:**	

Sample requirements : label with patient name, DoB and Pathology Block number
For DNA/RNA NGS Panel tests: Minimum of 50µm FFPE tissue sectioned at 6µm (8x6µm) or up to a maximum thickness of 10µm (5x10µm). It is important that sections are cut under conditions that prevent cross contamination from other specimens. **Samples with <20% neoplastic nuclei:** Send unstained tissue sections **(slide mounted)** on uncoated slides with a marked up H&E **Samples with >20% neoplastic nuclei:** Send unstained tissue sections **(as scrolls)** in a clean universal with a marked up H&E **For FISH tests :** Send 2x3µm unstained sections on coated slides, with a 1x3µm H&E **Please contact the laboratory if insufficient tissue available**
Sample Transportation Requirements: All slides should be packaged in a slide box for safe transportation to above address

For further information on sample requirements, guidelines relating to other sample types, and downloadable copies of this form, please see our departmental website https://bwc.nhs.uk/west-midlands-regional-genetics-laboratory

CONSENT STATEMENT It is the referring clinician's responsibility to ensure that the patient/carer knows the purpose of the test and that the DNA/RNA sample will be retained in long term storage and may be used for future diagnostic tests. Completing this form is an indication that the clinician has obtained consent for testing and storage. The patient should be advised that the sample may be used anonymously for quality assurance and training purposes. Please advise us of any restrictions. Any remaining sections/slides will be returned to the histopathology laboratory of origin.

East GLH DPYD genomic test ordering form

DPYD REFERRAL FORM

NHS
East Genomic Laboratory Hub

https://www.eastgenomics.nhs.uk/dpyd-testing/

Patient Details			Sample
NHS Number:	Hospital Number:	Family Number:	Sample type (EDTA):
Surname:	Forename(s):	Date of Birth:	Taken by (sign):
Sex:	Ethnicity:	Private Patient: ☐ Yes	Taken by (print name):
Address: Postcode:			Date sample taken: High risk of infection? ☐ Yes

Referring Clinician			
Name:	Hospital:	Speciality: Oncology	Telephone contact details:
Address: Postcode:		Personal Email address (nhs.net): Departmental/ team email (nhs.net) - required:	

Test required	Clinical Details
Please tick one: ☐ M1.7 - Colorectal carcinoma ☐ M3.7 - Breast cancer ☐ M6.5 Mucoepidermoid carcinoma ☐ M14.5 Adrenal cortical carcinoma ☐ M15.7 Head and neck squamous cell carcinoma ☐ M16.4 Adenoid cystic carcinoma ☐ M17.4 Secretory carcinoma (salivary gland) ☐ M219.3 Pancreatic cancer ☐ M220.3 Cholangiocarcinoma ☐ M222.4 Hepatocellular carcinoma ☐ M226.3 Cancer of unknown primary ☐ M227.3 Solid tumour other ☐ M119.4 Paediatric tumours ☐ M136.5 Fibrolamellar hepatocellular carcinoma - paediatric	Fluorouracil (5FU) ☐ Pre 5FU ☐ Post 5FU We accept the following samples: **3.5ml EDTA blood**

South West DPYD genomic test ordering form

Genomic Test Request

BRISTOL GENETICS LABORATORY
T: 0117 414 6168/6167/6174
nbn-tr.geneticsenquiries@nhs.net

EXETER GENOMICS LABORATORY
T: 01392 408229
Rde-tr.ExeterGenomicsLaboratory@nhs.net

NHS South West Genomic Medicine Service

Requesting organisation:

GLH laboratory:

Patient first name

Patient last name

Date of birth *(dd/mm/yyyy)*

Hospital number

Gender
☐ Male ☐ Female ☐ Other

Postcode

NHS number

Test Request (Include NHSE R/M code if known)

Relevant clinical information

Samples *(being sent to GLH DNA extraction lab)*

Sample ID	Collection date / time	Sample type	Sample volume	Comments

Responsible clinician / consultant

Name:
Department address:
Phone:
Email:

Main contact (if different from responsible clinician/consultant)

Name:
Department address:
Phone:
Email:

Additional copy to/ Preferred email address for reports:

Name: Email:

North East and Yorkshire DPYD genomic test ordering form

NHS North East and Yorkshire Genomics	**Genetics Referral Form** **DPYD (Dihidropyrimidine deoxygenase deficiency) genotyping**	**Lab Use Only** Lab No: Date received (dd/mm/yyyy):

Patient Information – use sticker if available				**Requesting Consultant Oncologist**	
NHS No:		**D.O.B (dd/mm/yyyy):**		**Full Name:**	
Surname:		**Sex:**		**Contact E-mail:**	
Forename:		**Hospital No:**		**Hospital:**	
Patient's Address:				**Ward /Clinic:**	
		Postcode:		**Address/Email for report:**	

Test Required – please refer to National Genomic Test Directory (https://www.england.nhs.uk/publication/national-genomic-test-directories/).

DPYD (Dihidropyrimidine deoxygenase deficiency) genotyping

Clinical details – including patient diagnosis and disease stage (if known)

Colorectal carcinoma	☐	Adenoid cystic carcinoma	☐
Secretory carcinoma (salivary gland)	☐	Mucoepidermoid carcinoma	☐
Breast cancer	☐	Hepatocellular carcinoma	☐
Pancreatic cancer	☐	Cancer of unknown primary	☐
Head and Neck squamous cell carcinoma	☐	Cholangiocarcinoma	☐
Adrenal coritical carcinoma	☐	Fibrolamellar hepatocellular carcinoma	☐

Other (please specify diagnosis if known)

Urgent? (Y/N)	Yes ☐ No ☐	**Telephone/Bleep for Urgent results:**	
Specimen details	**Sample Date (dd/mm/yyy):**	**Sample Time:**	
EDTA Blood (2. 5 ml tube)	☐		
	☐		

NHS Yorkshire and North East Genomic Laboratory Hub	**Once taken, samples should be sent URGENTLY to your local Genetics Laboratory (see below for contact information)**	
Newcastle Genetics Laboratory	Newcastle Genetics Laboratory Central Parkway Newcastle upon Tyne Tyne and Wear NE1 3BZ	nuth.cancer.genomics@nhs.net **0191 241 8786** www.newcastlelaboratories.com/lab_service/laboratory-cancer-services/
Sheffield Genetics Laboratory	Sheffield Diagnostic Genetics Service Sheffield Children's NHS Foundation Trust Western Bank Sheffield S10 2TH	sheffield.diagnosticgenetics@nhs.net **0114 271 7014** www.sheffieldchildrens.nhs.uk/SDGS.htm
Leeds Genetics Laboratory	Leeds Genetics Laboratory Genomic Specimen Reception Bexley Wing (Level 5) St James's University Hospital Beckett Street Leeds, LS9 7TF	leedsth-tr.DNA@nhs.net **0113 206 7594** www.leedsth.nhs.uk/a-z-of-services/the-leeds-genetics-laboratory/

North Thames genomic test ordering form

Clinical Genomics Department
The Centre for Molecular Pathology
The Royal Marsden NHS Foundation Trust
15 Cotswold Rd, Sutton, Surrey SM2 5NG
Tel: 0208 915 6565
rmh-tr.moleculardiagnostics@nhs.net
cytogenetics@icr.ac.uk

North Thames Genomic Laboratory Hub
The ROYAL MARSDEN NHS Foundation Trust

Patient and sample details:	**Destination of report:**
Name: _____	Name: _____
Date of birth: / / Male ☐ Female ☐	Hospital:_____
Hospital No. _____	Department:_____
NHS No. _____	Address:_____
Histopathology Lab No. _____	_____
Date taken: / /	_____
Diagnosis/tumour type:_____ Stage:	_____
Specimen type:_____	Copy report to (NHS.NET contact):
Tissue type: Biopsy ☐ Resection ☐	_____
Primary ☐ Metastasis ☐	Sender's contact name and phone/email details:

☐ NHS patient ☐ Private patient ☐ Other

Please provide details for billing information if different from the requesting hospital above.

SOLID TUMOUR DNA NGS PANEL

Colorectal ☐ ***Lung*** ☐ ***Melanoma*** ☐ ***Thyroid*** ☐ ***GIST*** ☐
Bladder ☐ ***H&N*** ☐ ***Prostate*** ☐ ***Liver*** ☐ ***Renal*** ☐
Breast ☐ ***Pancreatic*** ☐ ***Adrenal*** ☐
Neurological ☐ ***Endometrial*** ☐ ***Salivary Gland*** ☐ ***Cholangiocarcinoma*** ☐
OTHER (please specify) ☐ _____

Please send 1 H&E section with the tumour area clearly marked and 5 x 10 µm mounted sections (unstained, uncharged)

PAN-CANCER RNA NGS PANEL

Sarcoma ☐ ***Lung*** ☐ ***NTRK*** ☐ ***H&N*** ☐ ***Thyroid*** ☐
Renal ☐ ***Bladder*** ☐ ***Prostate*** ☐ ***Salivary gland*** ☐
OTHER (please specify) ☐ _____

Please send 1 H&E section with the tumour area clearly marked and 5 x 10 µm mounted sections (unstained, uncharged)

FISH (please specify probes) ☐ _____ ***MDM2*** ☐

Please send 1 H&E section with the tumour area clearly marked and 2 x 2 µm mounted sections per FISH probe (unstained, positively charged)

Please send samples to the address above

Please tick the appropriate box according to your local pathology assessment of the tissue sent for testing:

Cellularity: ☐ **High** ☐ **Intermediate** ☐ **Low** ☐ **Very Low**

Neoplastic nuclei: ☐ **>70%** ☐ **50-70%** ☐ **30-50%** ☐ **20-30%** ☐ **10-20%**

Necrotic: ☐ **YES** ☐ **NO** **High Melanin content:** ☐ **YES** ☐ **NO**

North West genomic test ordering form

UKAS MEDICAL 9322

Caution Biological hazard

GENETICS LABORATORIES TEST REQUEST

Please PRINT clearly in black ball point pen as this form will be scanned

NHS North West
NHS Genomic Laboratory Hub

Surname:	**Date of Birth:**	**Genetics Laboratory ID:** FOR GENETICS
First name:	**Birth Gender:**	
NHS number:	**Hospital No:**	**Date/time received:** LABORATORY
Hospital:	**G Number:**	
Home Address:	**NHS** ☐ **Private** ☐	**Sample type/volume:** USE ONLY
	Postcode:	
Referring clinician: (PRINT SURNAME)	**Signature:**	**First sample review:**
		Sample collection:
Dept / Surgery:	**Contact Tel number:**	**Time:** / **Signature:**
E-mail address:	**Fax No:**	**Date:**

TEST REQUIRED (see overleaf for sample requirements)

- ☐ DNA Storage EDTA
- ☐ Microarray EDTA
- ☐ Gene/panel test EDTA
  Please Specify below
- ☐ FISH
- ☐ Karyotyping
- ☐ Fixed cell Storage Lith Hep

SAMPLE TYPE

- ☐ Amniotic Fluid (AF)
- ☐ Blood Lith Hep
- ☐ Buccal Scrape/Saliva sample
- ☐ Chorionic Villus Sample (CVS)
- ☐ Solid Tissue (specify origin) .....
- ☐ Other .....
- ☐ Blood EDTA
- ☐ Bone Marrow
- ☐ Solid Tumour
- ☐ Urine

REASON FOR GENE/PANEL TEST

- ☐ Mutation Screen / Diagnostic Test
- ☐ Predictive Test (asymptomatic)
- ☐ Carrier Test (recessive disorder)
- ☐ Family studies
- ☐ Other.....

HIGH RISK SAMPLES:

If a specimen is known to present an infection hazard it must be clearly labeled 'DANGER OF INFECTION' and the infection hazard stated

VIRAL HEPATITIS B	YES	NO
OTHER HIGH RISK INFECTION	YES	NO

Please Specify:.....

Disease / Clinical Details - Please give clinical details and full family history (if any). If pregnant please indicate gestation in section below.

Consent to store (see overleaf)
Please tick if patient does **NOT** want any remaining DNA/RNA or fixed cell suspensions stored in the laboratory ☐

CONTACT INFORMATION
Tel: 0151 702 4228 / 4229
Fax: 0151 702 4230
www.liverpoolwomens.nhs.uk
generic email: (monitored daily)
dna.liverpool@nhs.net
Oncology section specific email:
mft.genetics-oncology@nhs.net

PLEASE DELIVER TO:
North West Genomic Laboratory Hub (LIVERPOOL)
Manchester Centre for Genomic Medicine,
Liverpool Women's Hospital,
Crown Street,
Liverpool, L8 7SS

GRAVIDA:..... **PARA:**..... **L.M.P:**.....
Age by Scan:..... **Partner name:**..... **Partner DOB:**.....

NHS North West NHS Genomic Laboratory Hub

NB Illegible request forms, or inadequately labeled containers, may delay processing

Doc ref: GEN 686: v1.3 Feb 2020. Authorised: ES

South East DPYD genomic test ordering form

DPD-5FU Request Form

Innovation, Collaboration and Expertise

viapath

Prefix Label

Patient Details			Requesting Client Code/Address
Surname			
Forename/s			
Date of Birth			
Gender (M/F)			
NHS/Hospital Number			
Sample Date/Time	...../...../.....	:	

Requesting Clinician		Clinical Details
Name		*Reason for request/relevant history*
Number		
Email		

Sample Type	Test/s Requested	Fluorouracil (5FU)
3.5ml EDTA Blood	☐ **DPD-5FU** (BDPD5FU)	☐ **Pre 5FU** ☐ **Post 5FU**

Originating/Referring Lab Number* (OLN/RLN)
**Also known as Outside Case Number*

OLN/RLN statement required RE: payment/billing

Packaging instructions	Invoice To *(if different to report address)*
Packaging for samples sent via Royal Mail must comply with PI 650 for Category B substances.	

Send Samples to;
Purine Research Laboratory, 4th Floor, North Wing, St Thomas' Hospital, Westminster Bridge Road, London, SE1 7EH
Enquiries: 020-718-88008 Viapath.Customersupport@nhs.net

South East PoC data set.

Data Elements Entry

M16	M16.4	**Patient Data:** First Name Last Name Date of Birth NHS Number OE Patient Number GP Practice Code Patient Ethnicity	**Request Data:** CI Requested CITT Requested OE Name OE ODS Code OE Order Ref Requestor Name Requestor e-mail Requestor Tel. No. Pre/post- chemo	**Sample Data:** OE Sample Type OE Sample Volume OE Sample ID Courier Method Temperature Control	**Results Data:** Lab Request Ref Requested CITT Lab Sample Type Results Test Methodology Results document ref Variant Level Results OE Order Ref NHS Number Lab Patient Number OE Sample ID

Appendix 1

DPYD Testing - Sample Collection Pack

Sample type:

5ml peripheral blood collected into an EDTA tube (pink/purple lid)

Sample collection and referral forms:

Please note that samples that are unlabelled, poorly labelled or illegible will not be processed by the laboratory.

It is the responsibility of the healthcare professional who is supervising sample collection to ensure that patient's sample is collected into an appropriately labelled tube. The tube label should include **3 sufficient identifiers** to uniquely identify the sample. Identifiers would normally include surname, forename and date of birth, but should also include the NHS number where this is available.

All samples should be accompanied by a referral form that includes the patient's demographic information, the clinician's details, the reason for referral and the specific test that is being requested. It is also important that the referral card includes information about the person to whom the results are to be reported to. *Please see enclosed examples of how to complete the NW GLH referral forms*

A local procedure should be in place to ensure that the information on the referral form matches the demographic information on the specimen tube. Please note that the laboratory cannot normally process specimens where this information is mismatched due to risks that this poses to patient safety.

Local procedures should be in place to ensure the safety of the staff and patient during sample collection.

'High-risk' samples:

The person sending the sample to the laboratory has a legal responsibility to inform the laboratory staff if the sample poses a high risk to other health professionals. This would normally take the form of a 'high-risk specimen' sticker which is applied to the referral form and tube along with an indication on the referral form about the nature of the risk (e.g. Hepatitis C positive).

Please note that special care should be taken for the packaging and transportation of these high-risk samples and depending on the risk they may require different arrangements. Please consult the following document for more details: http://www.hse.gov.uk/biosafety/biologagents.pdf

Packaging:

Please note that this information is a short summary. More detailed information is available from the Health & Safety Executive and available here: http://www.hse.gov.uk/biosafety/biologagents.pdf

Patient specimens are classified as Category A or B depending on the pathogen they either are known to contain, or potentially contain. There are much stricter regulations concerning packaging, training and security that apply to Category "A" material however this category mainly applies to infectious substances capable of causing disease in humans or animals and since it is unlikely that any Category A packages will be sent into the lab directly they will not be covered in this summary.

Everything that is not Category A is Category B. The correct shipping name for Category B is Biological Material, Category B, the identification number is "UN 3373" and the material must be packaged in compliance with Packing Instruction 650.

The package labelling must include:

- The UN 3373 hazard diamond and a "Biological Material, Category B" label on the outer package.
- Rolls of "stick on" combination UN 3373 diamond/ "Biological Material, Category B" labels are available from specialist label suppliers.
- The name and address of both the sender and receiving centre.
- The name and telephone number of a "Responsible Person" who is familiar with the contents and the hazards it may pose is required either on the waybill if a courier is used, or on the package itself.

Packaging Instruction 650 outlines the labelling and testing requirements for packing used in the transportation of Biological Material, Category "B".

In practice, the package should include:

- Primary receptacle that is leak-proof and contains no more than 1L or 1 Kg of specimen including fixative or transport media if being sent by road (50 ml/50 mg by post).
- Layer of absorbent material sufficient to absorb the entire volume of any liquid contents in the package.
- Secondary packaging that is leak-proof with a maximum content of 4 L/4 Kg per outer packaging if sent by road (50 ml/50 mg by post).