NHS
Greater Manchester
Cancer Alliance

HPB Genomic Champions Workshop

Clinical Lead: Dr Victoria Foy
Project Managers: Simran Chander,
Lisa Heys

Greater Manchester Cancer
Academy

Learning Objectives

- Understand current pathway
- Discuss why molecular testing is important and how it impacts treatment options
- Establish the role of the genomics champion
- Learn how to request molecular testing
- Understand reflex testing pathway

Learning Objectives

- Understand current pathways and pitfalls

Pathways in HPB

- Biliary tract cancer
- Pancreatic cancer
- Primary liver cancer

Current patient pathway

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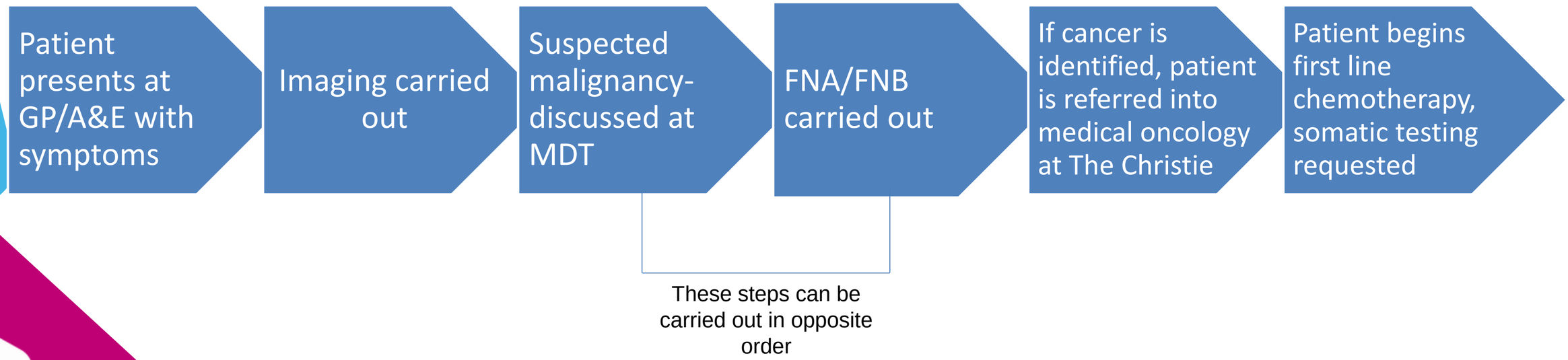

Challenges with the current pathway

- Proportion of patients referred with cytology alone
- Molecular testing requested for a proportion of patients
- Delays to obtaining molecular testing results

Challenges with the current pathway

- Proportion of patients referred with cytology
- Molecular testing requested for a proportion of patients
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Tissue is the issue!! Pancreas

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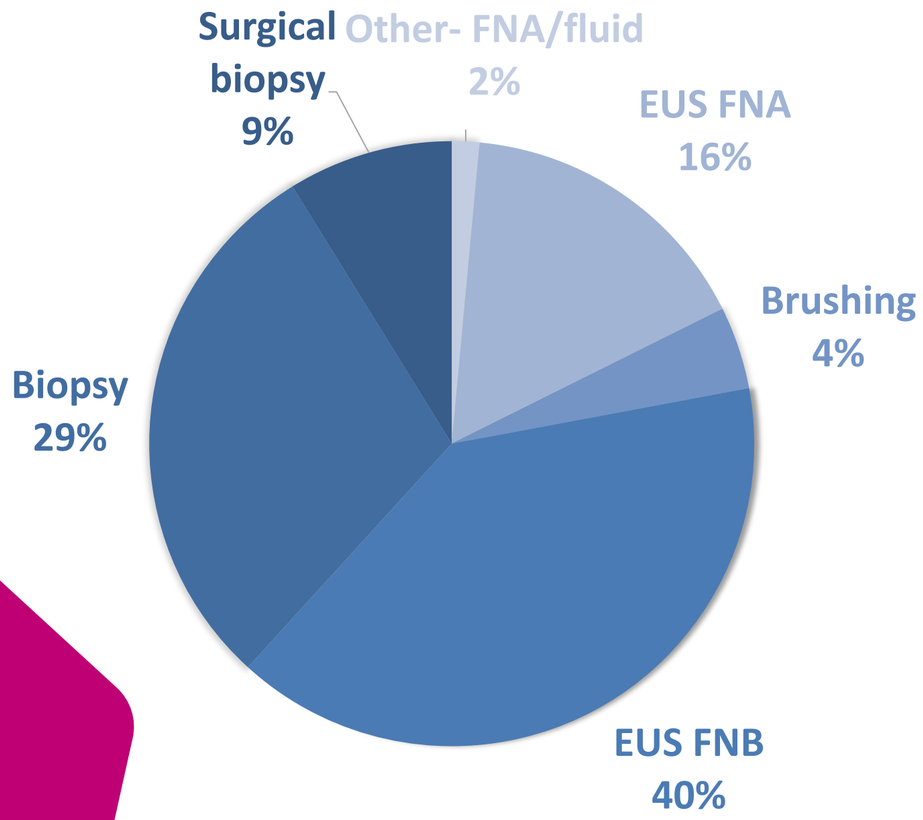
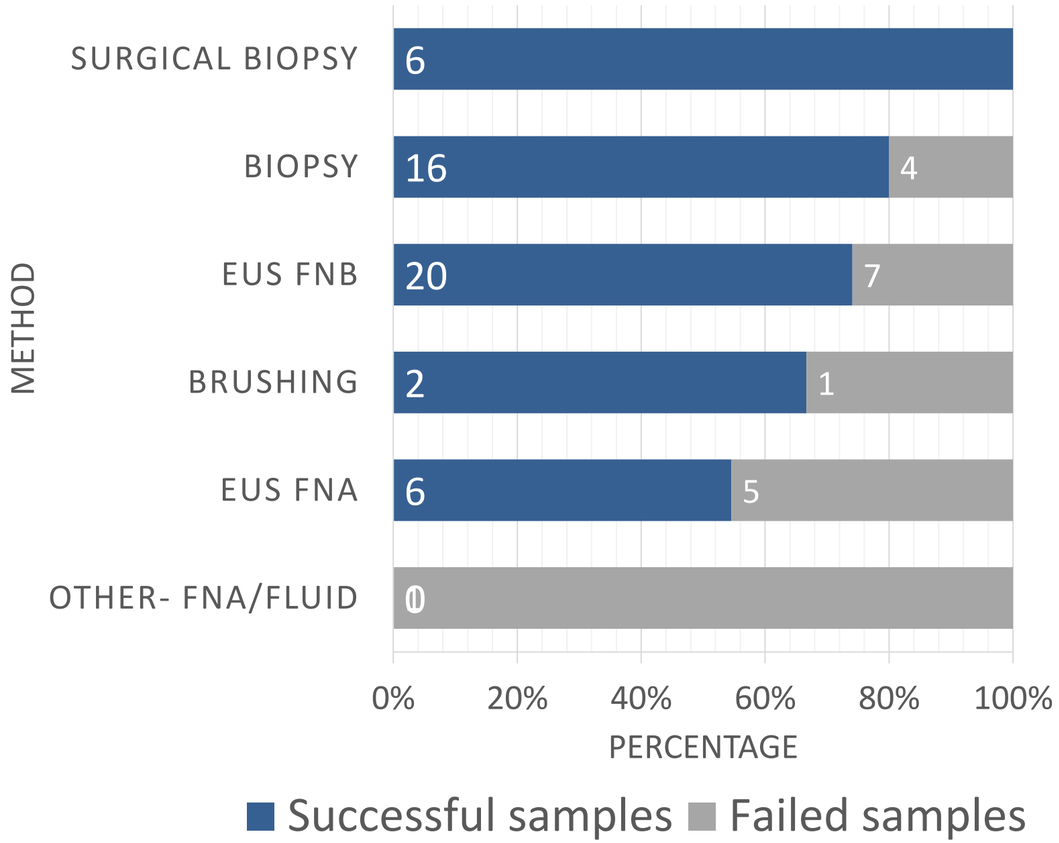
Molecular Profiling by Method (N=68)



Molecular Profiling Success Rate Based on Method



Denise Ng

Tissue is the issue!! Biliary tract

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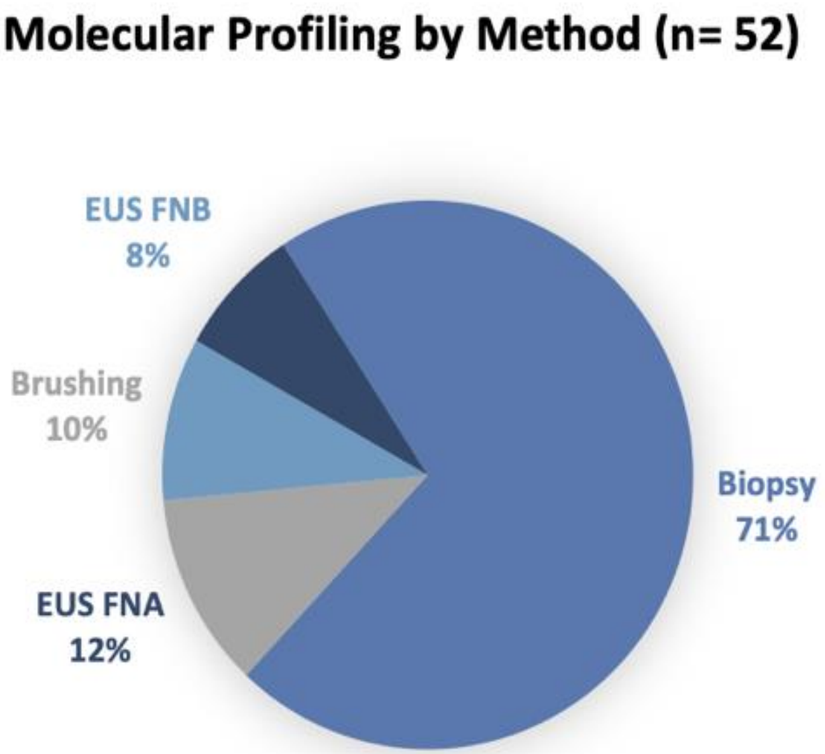

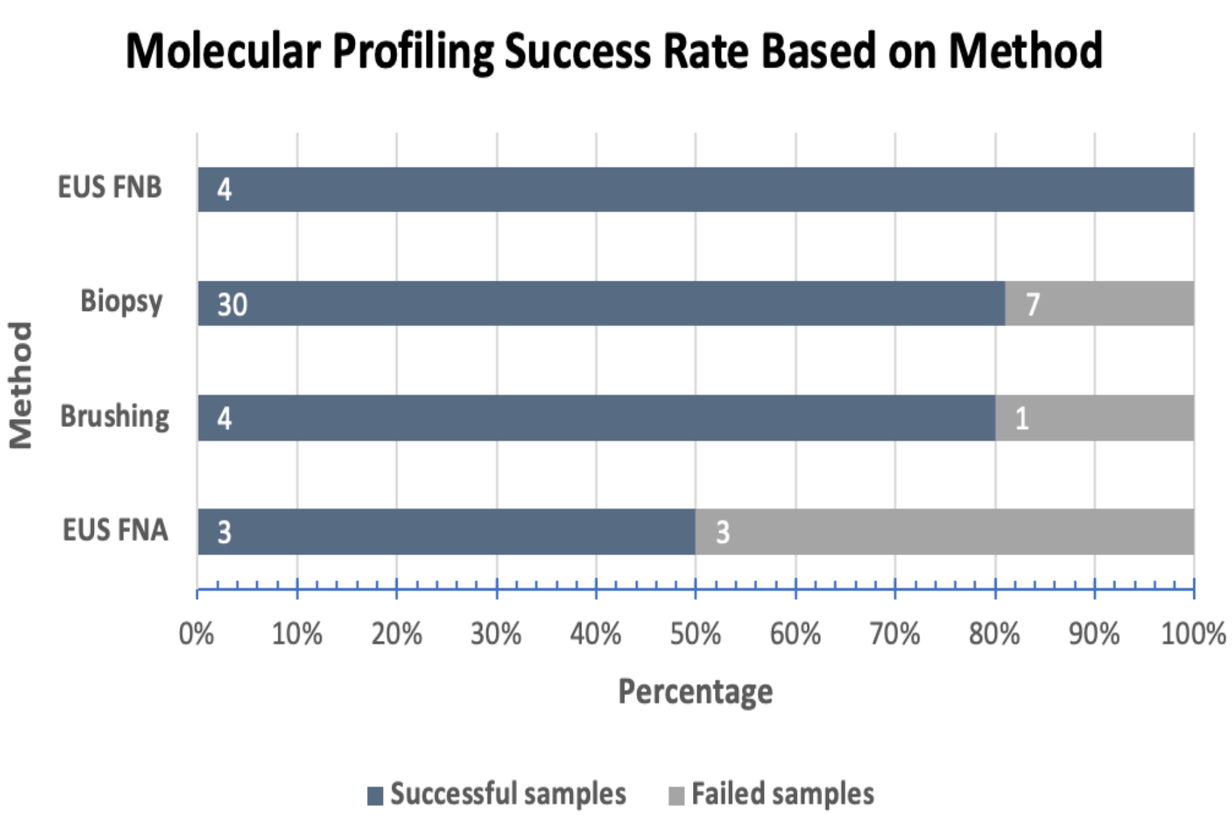

Alia Alothman

Challenges with the current pathway

- Proportion of patients referred with cytology alone
- Molecular testing requested for a proportion of patients
- Delays to obtaining molecular testing results

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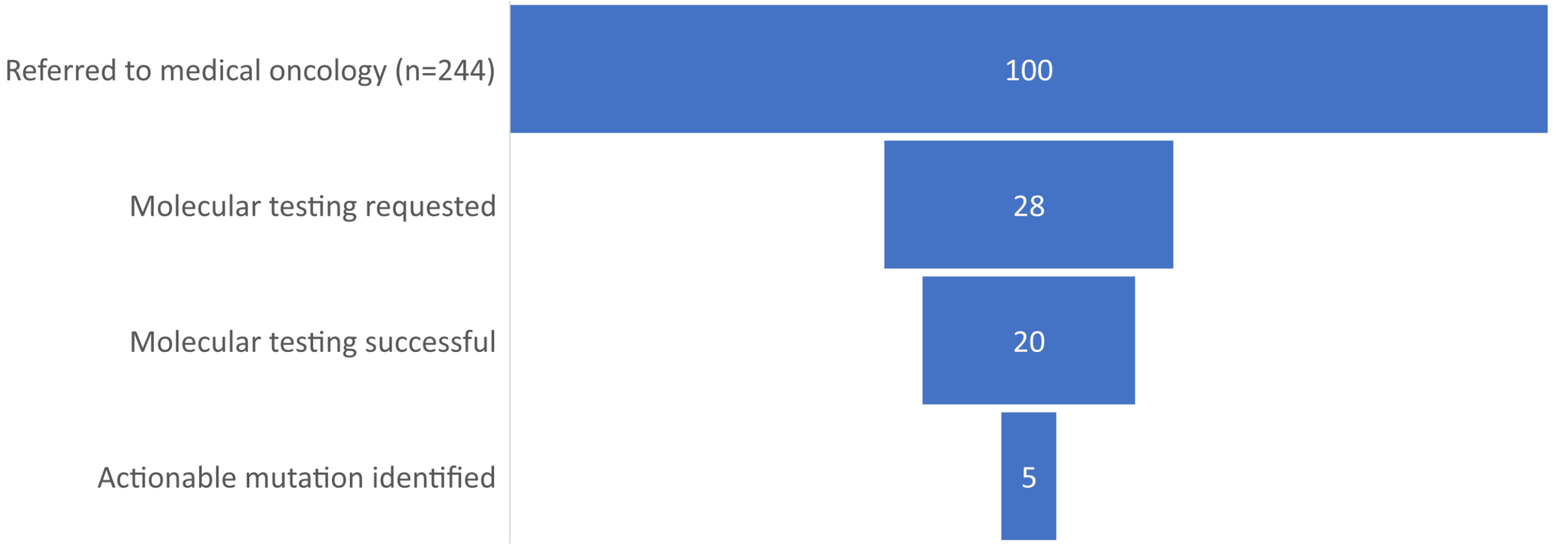
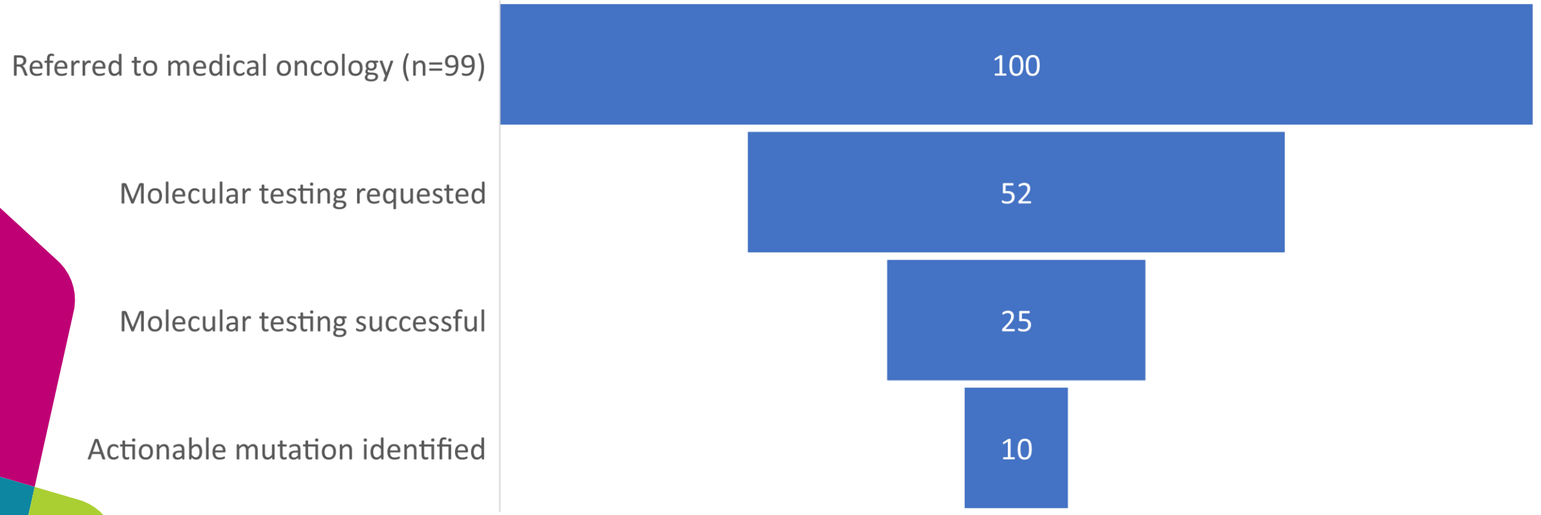
Percentage of patients with molecular testing advanced pancreatic cancer 2021-2022



Percentage of patient with molecular testing in advanced cholangiocarcinoma 2022-2023



Denise Ng, Alia Alothman

Challenges with the current pathway

- Proportion of patients referred with cytology alone
- Molecular testing requested for a proportion of patients
- Delays to obtaining molecular testing results

Proportion of patient receiving second line treatment – CCA

The rapid decline in performance status on progression following first-line chemotherapy in patients with ABC.

Published data suggest that between 15% and 25% of patients might be fit enough to receive second-line chemotherapy.

1.Second-line chemotherapy in advanced biliary cancer: a systematic review. Lamarca, A. et al.Annals of Oncology, Volume 25, Issue 12, 2328 - 2338

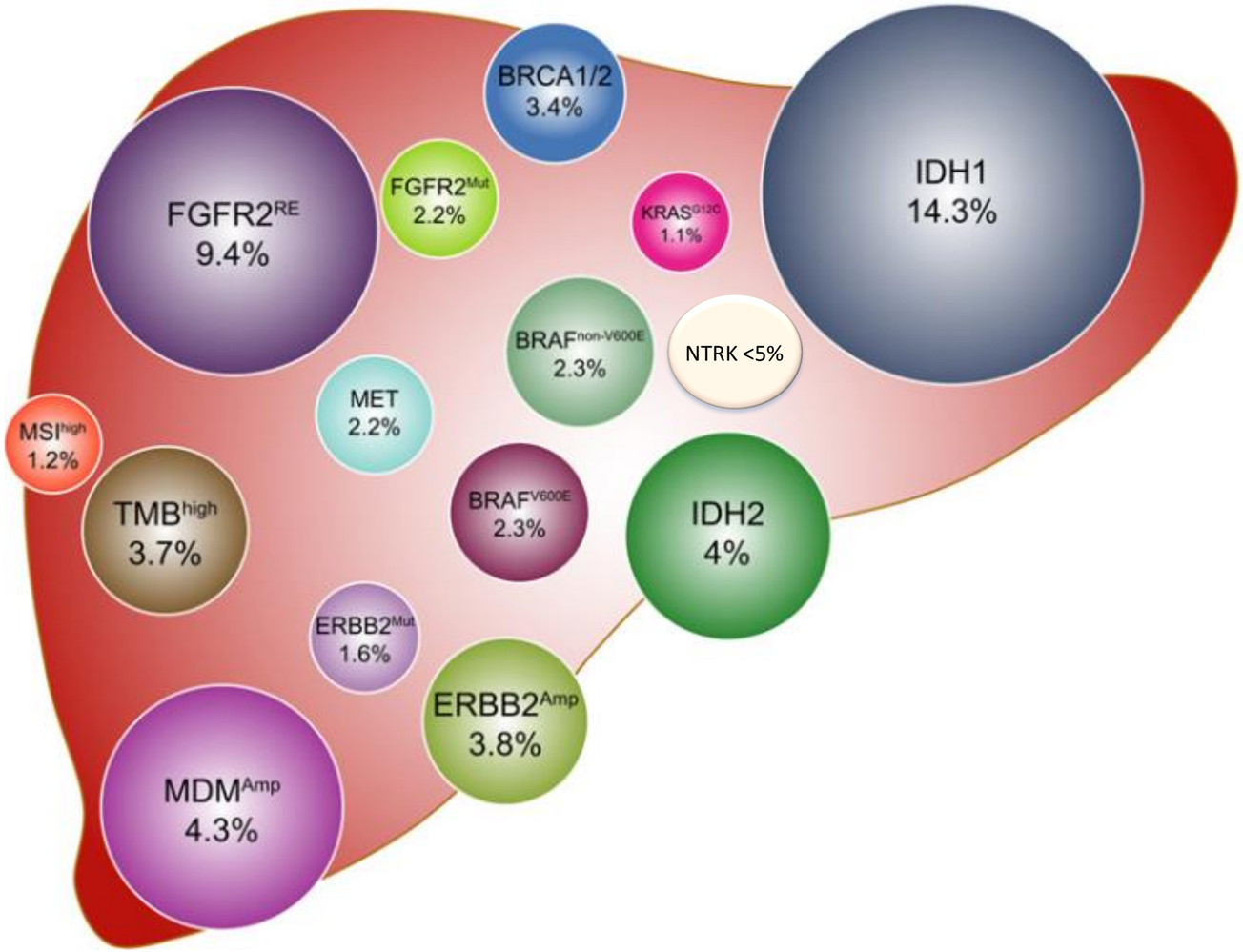
Improvements to the current pathway

- Proportion of patients referred with cytology alone
  - All patients to have a diagnostic FNB/ biopsy to allow for molecular testing
- Molecular testing requested for a proportion of patients
  - All patient who are deemed fit enough to receive systemic therapy have molecular testing requested.
- Delays to obtaining molecular testing results
  - Molecular testing is requested at point of referral to medical oncology.

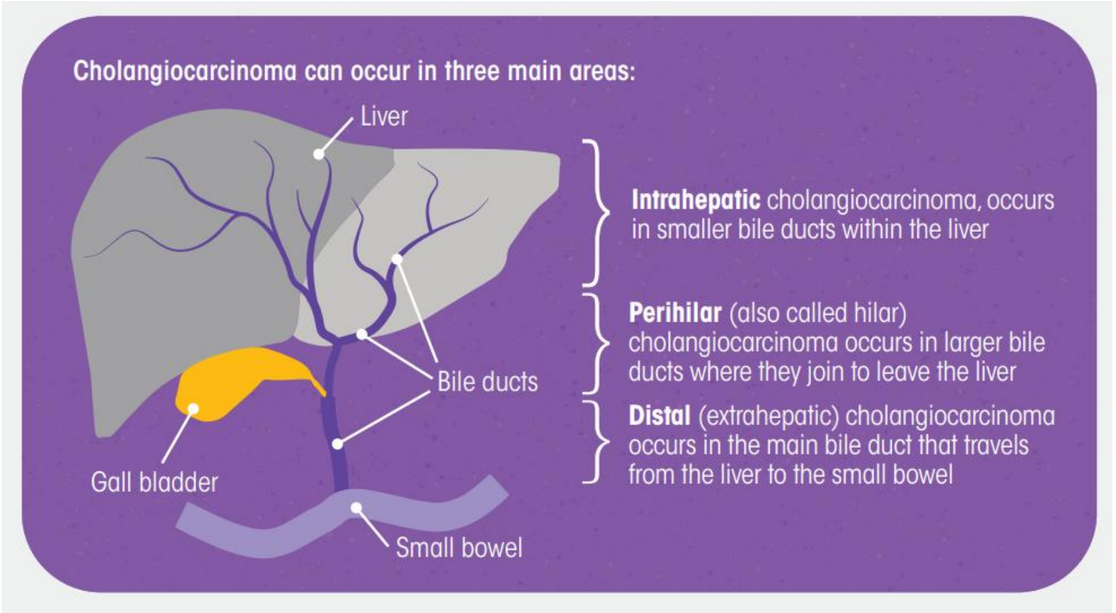
Learning Objectives

- Understand current pathways ☑
- Discuss why molecular testing is important and how it impacts treatment options

Molecular alterations in cholangiocarcinoma



Adapted From Lamarca, A. et al. J. Hepatol. 2020



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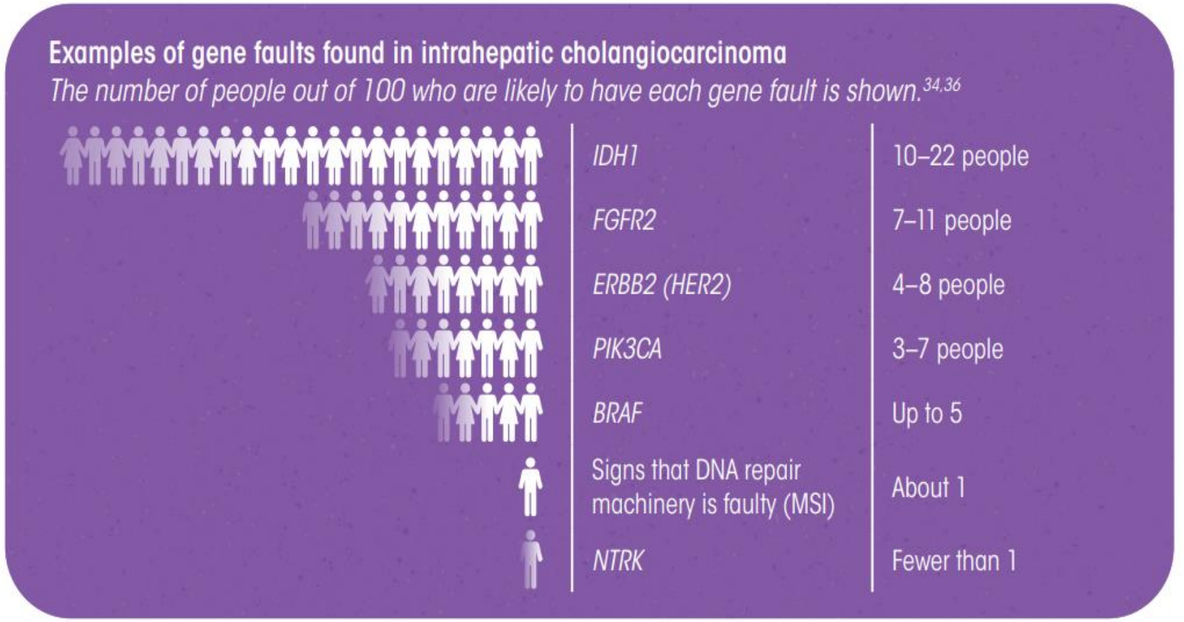

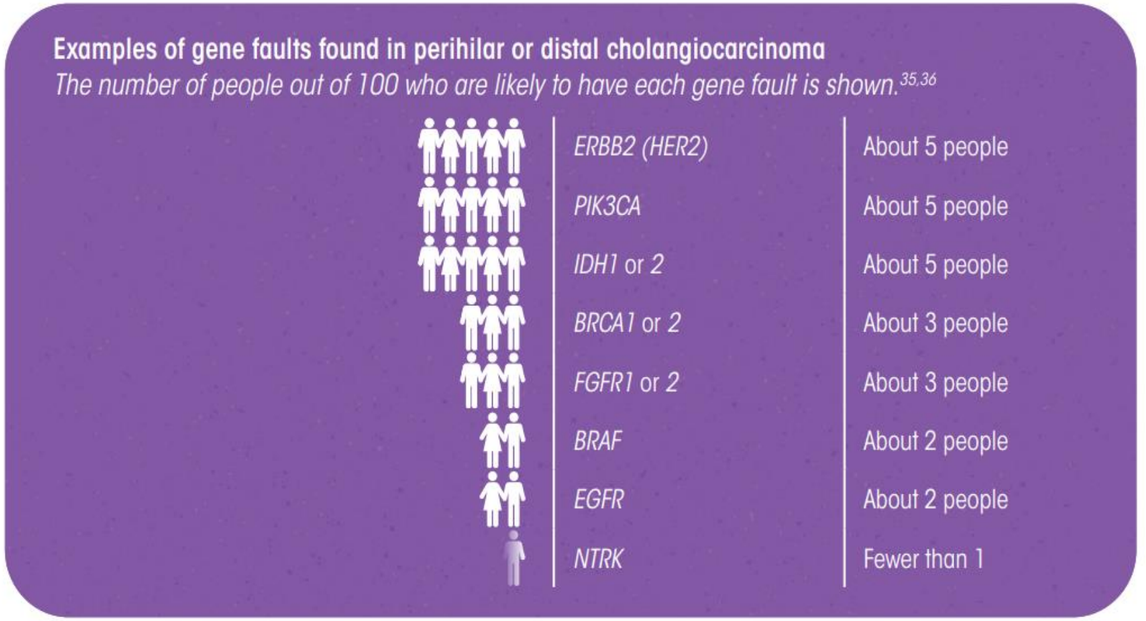

- AMMF website : https://ammf.org.uk/treatment-options/ accessed 30/09/24

Efficacy of target medicine

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SOC chemotherapy (FOLFOX)

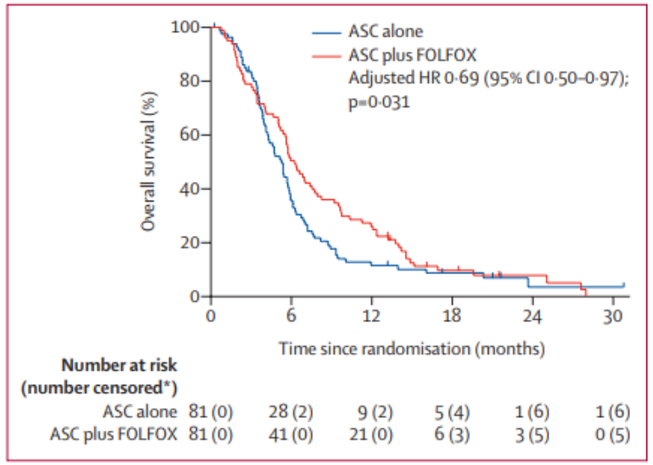
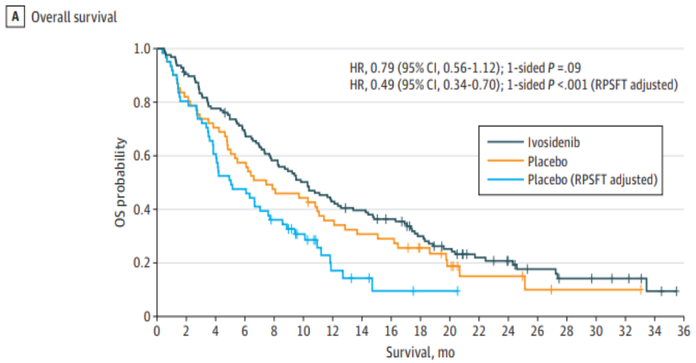


Figure 2: **Overall survival**
The HR is adjusted for the three stratification factors (platinum sensitivity, serum albumin concentration, and disease stage). ASC=active symptom control. FOLFOX=folinic acid, fluorouracil, and oxaliplatin. HR=hazard ratio. *Numbers are cumulative.

FOLFOX
Median overall survival 6.2 months

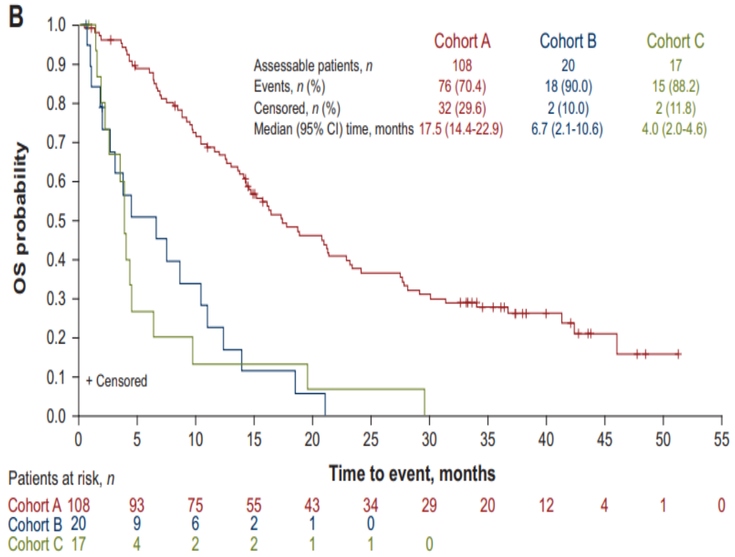
IDH1 mutation



Treatment group	Events/patients, No.	OS, median (95% CI), mo
Ivosidenib	100/126	10.3 (7.8-12.4)
Placebo	50/61	7.5 (4.8-11.1)
Placebo adjusted by RPSFT	49/61	5.1 (3.8-7.6)

Ivosidenib
Median overall survival 10.3 months

FGFR2 fusion



Pemigatinib
Median overall survival 17.5 months

1) Second-line FOLFOX chemotherapy versus active symptom control for advanced biliary tract cancer (ABC-06): a phase 3, open-label, randomised, controlled trial Lamarca, Angela et al. The Lancet Oncology, Volume 22, Issue 5, 690 – 701
2) Final Overall Survival Efficacy Results of Ivosidenib for Patients With Advanced Cholangiocarcinoma With IDH1 Mutation: The Phase 3 Randomized Clinical ClarIDHy Trial. Zhu AX, Macarulla T, Javle MM, et al. JAMA Oncol. 2021, 7(11):1669–1677
3) An open-label study of pemigatinib in cholangiocarcinoma: final results from FIGHT-202☆Vogel, A. et al. ESMO Open, Volume 9, Issue 6, 103488

NICE approvals

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Larotrectinib for treating NTRK fusion-positive solid tumours (27 May 2020)

Pemigatinib for relapsed or refractory advanced cholangiocarcinoma with FGFR2 fusion or rearrangement (25 Aug 2021)

Pembrolizumab for previously treated BTC with high MSI or MMR deficiency (20th Sep 2023)

Ivosidenib as an option for treating locally advanced/ metastatic cholangiocarcinoma with an IDH1 R132 mutation in adults after 1 or more systemic treatments (14 Dec 2023)

Futibatinib for treating locally advanced or metastatic cholangiocarcinoma FGFR2 fusion or rearrangement that has progressed after at least 1 line of systemic treatment (11th Sept 2024)

BTC biliary tract cancer, MSI microsatellite instability, MMR mismatch repair deficie

Testing currently available – somatic

Pancreatic cancer (M219)	Cholangiocarcinoma (M220)	Hepatocellular carcinoma (M222)
DYPD	DYPD	
NTRK1/ NTRK2/ NTRK3	NTRK1/ NTRK2/ NTRK3	NTRK1/ NTRK2/ NTRK3
MSI	MSI	
BRCA1/ BRCA 2	FGFR2	
	IDH1	

Targeted therapies in cholangiocarcinoma

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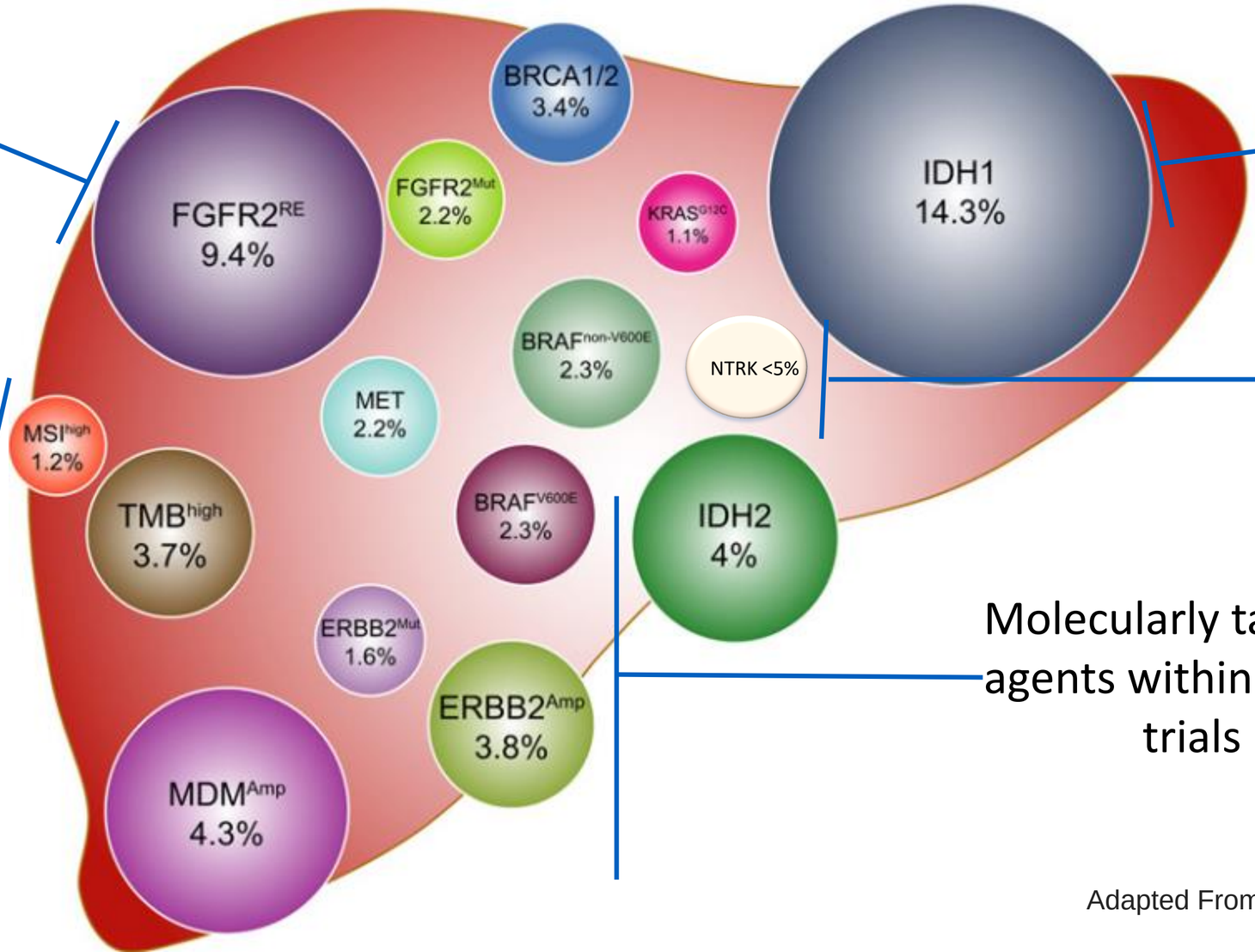
Pemigatinib
Futibatinib

Pembrolizumab



Ivosidenib

Larotrectinib
Entrectinib

Molecularly targeted agents within clinical trials

Adapted From Lamarca, A. et al. J. Hepatol. 2020

Treatment pathways – Biliary tract cancer

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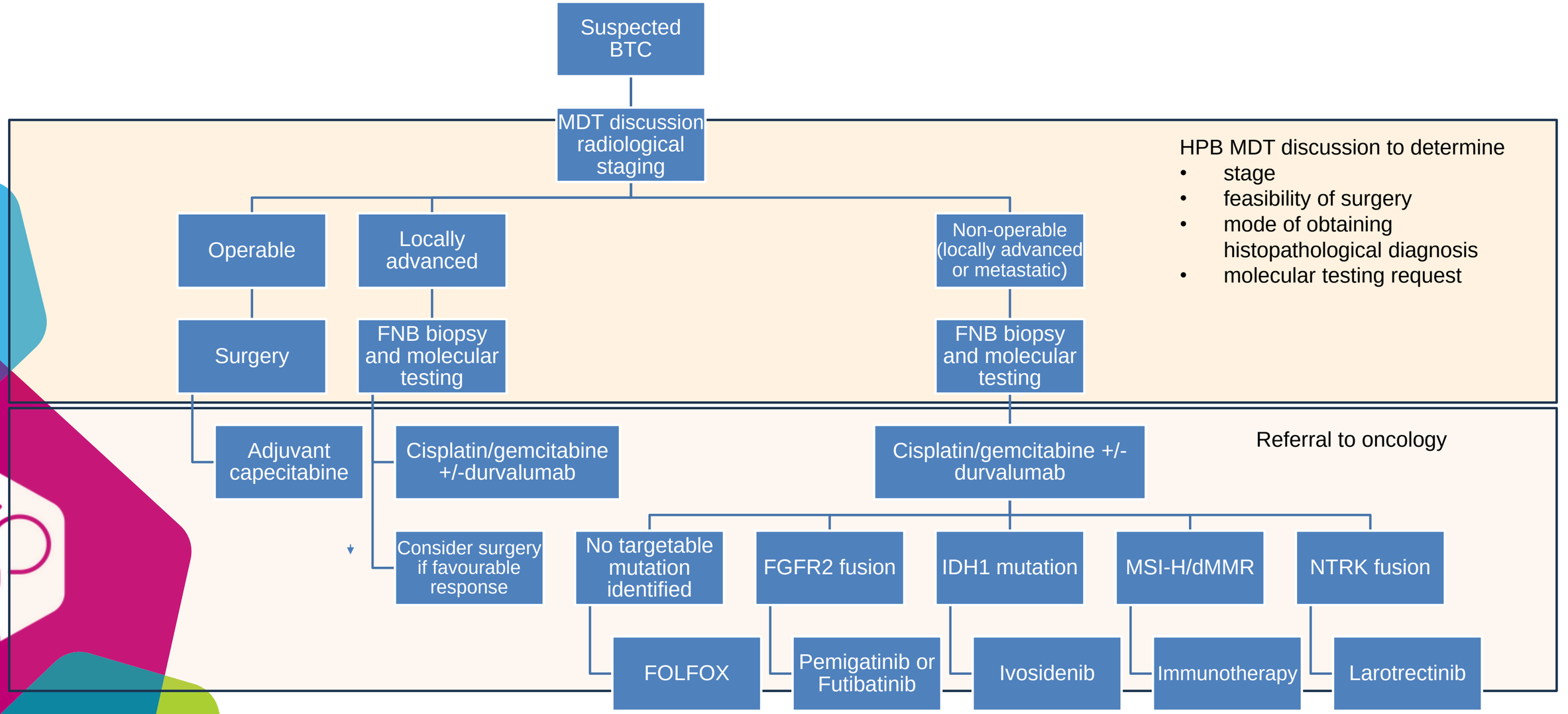

Precision medicine in pancreatic cancer

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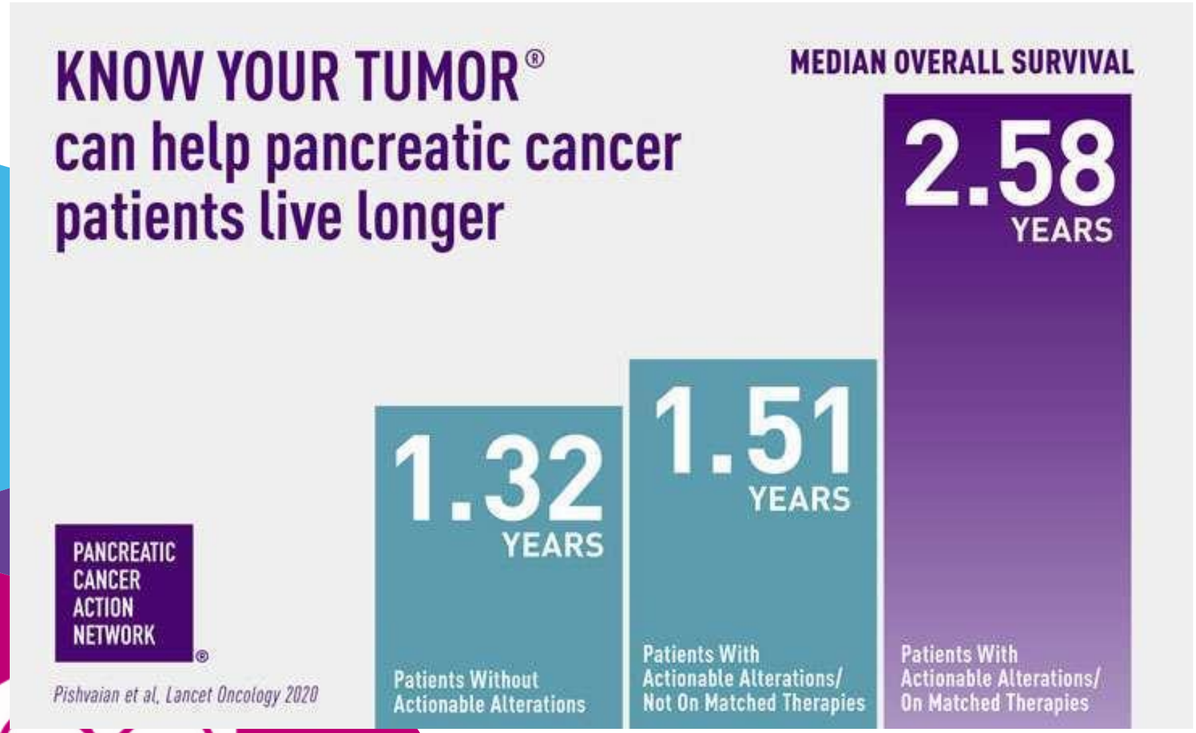


Overall survival in patients with pancreatic cancer receiving matched therapies following molecular profiling: a retrospective analysis of the Know Your Tumor registry trial

Michael J Pishvaian MD, Edik M Blais PhD, Jonathan R Brody Prof, Emily Lyons BS, Patricia DeArbeloa MD, Andrew Hendifar MD, Sam Mikhail MD, Vincent Chung MD, Vaibhav Sahai MD, Davendra P S Sohal MD, Sara Bellakbira BS, Dzung Thach PhD, Lola Rahib PhD, Subha Madhavan PhD, Lynn M Matrisian Prof and Emanuel F Petricoin Prof

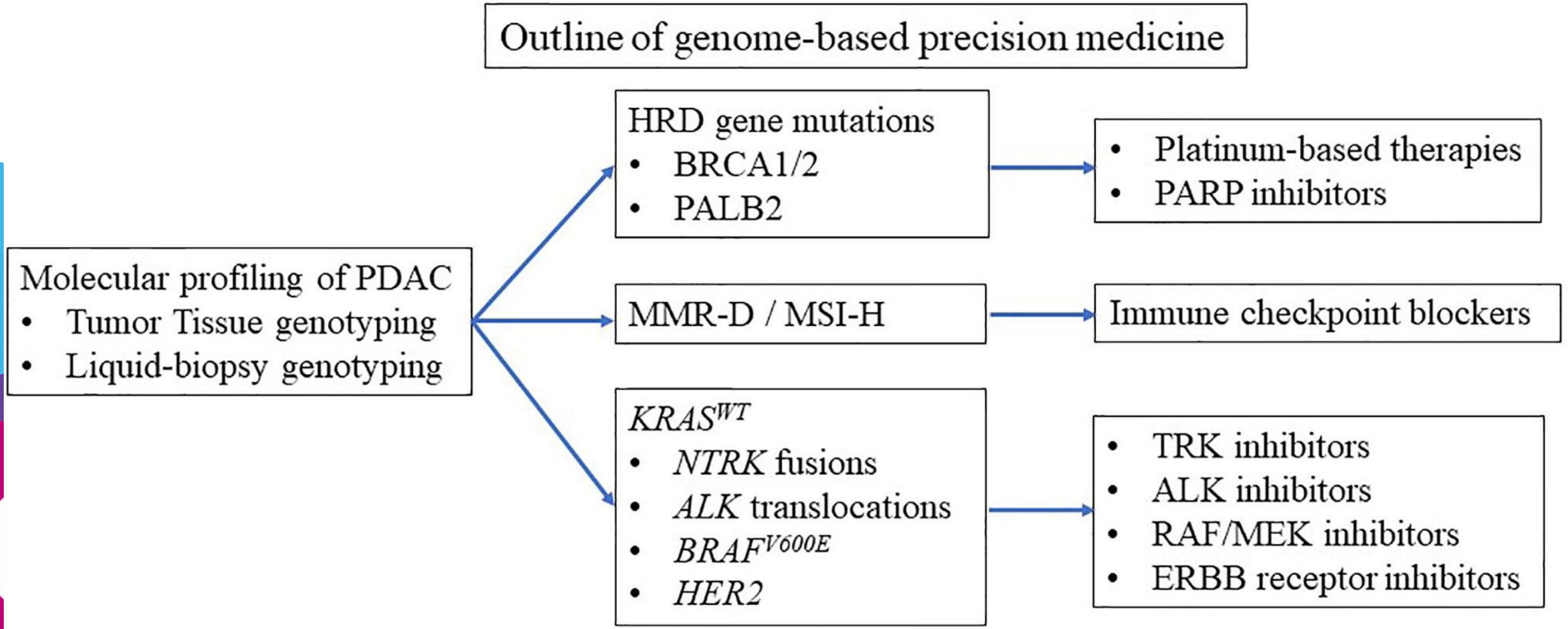
Lancet Oncology, The, 2020-04-01, Volume 21, Issue 4, Pages 508-518, Copyright © 2020 Elsevier Ltd

FDA-approved precision-based therapies potentially available in PDAC

***BRCA* mutations: olaparib**
NTRK fusions: Larotrectinib[a], entrectinib[a]
MSI-H status: Pembrolizumab[a]
BRAF mutations: Encorafenib/binimentinb
ROS1 fusions: Entrectinib
ALK fusions: Crizontinib, ceritinib, alectinib
RET fusions: Pralsetinib
NRG1 fusions: Afatinib

https://pancan.org/news/pancans-know-your-tumor-can-help-pancreatic-cancer-patients-live-longer/ Accessed 02/10/2024
Casolino R, Biankin AV. Treatment of pancreatic cancer in 2022. Cambridge Prisms: Precision Medicine. 2023;1:e14. doi:10.1017/pcm.2023.2

Precision medicine in pancreatic cancer



Miyabayashi K, Nakagawa H, Koike K. Molecular and Phenotypic Profiling for Precision Medicine in Pancreatic Cancer: Current Advances and Future Perspectives. Front Oncol. 2021 Jun 23;11:682872. doi: 10.3389/fonc.2021.682872. PMID: 34249730; PMCID: PMC8260689

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Case Study

Case study 1

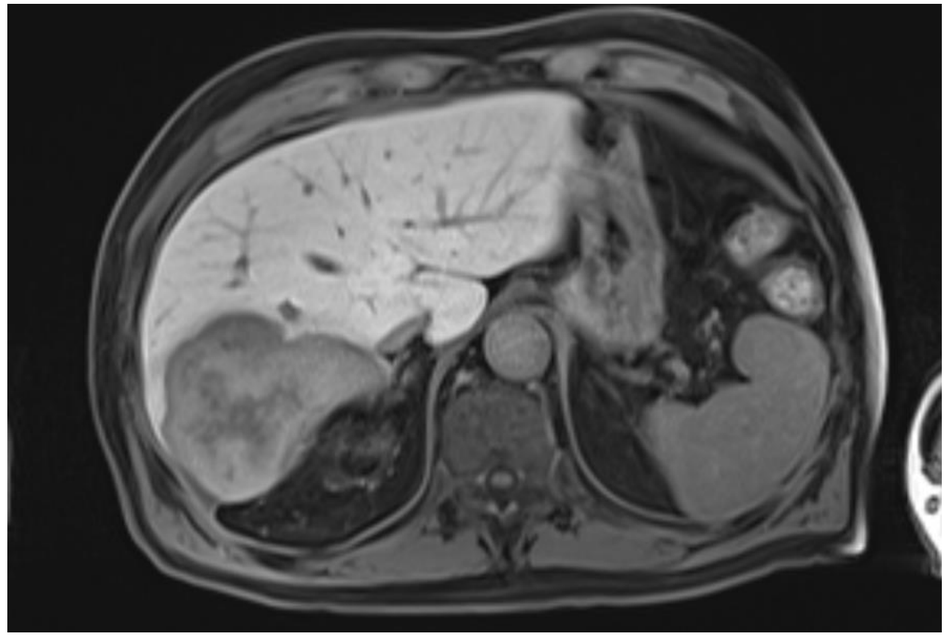
83 year old gentleman

Presented with weight loss and reduced appetite

PMHx HTN

PS 1

- US guided biopsy- adenocarcinoma
- Surgery: Hemihepatectomy
and cholecystectomy for intrahepatic cholangio
- 11cm tumour pT2 R1



Case study 1

Resected : 11cm tumour pT2 R1 iCCA

Ref medical oncology : offered adjuvant trial (ACTICA cis/gem) or SOC adjuvant capecitabine.

Received 8 cycles of adjuvant capecitabine

2 dose reductions
25% c2-5
50% c6-8

Discharged back to local follow up

Case study 1

Re-referred to medical oncology 24 months later

Mediastinal nodes and lung mets (small volume)

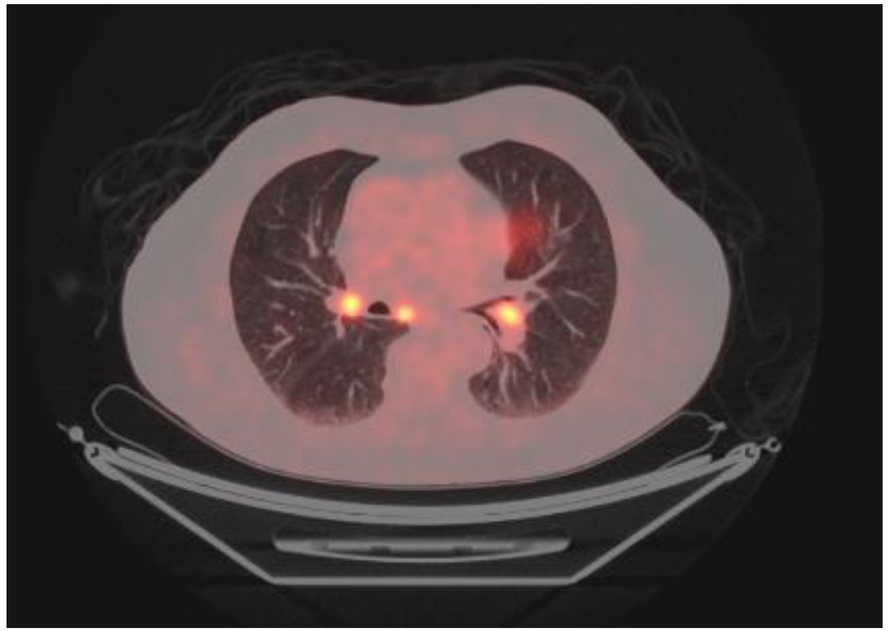
Surveillance for 6 months

Stable lung changes, new liver mets

Referred for consideration of radiotherapy

Radiotherapy to the liver.

Path send for molecular testing.



Case study 1

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RESULTS:

NAME (DoB)	PATH SAMPLE REF	RESULT
[redacted]	M[redacted]-18 A2	**NO FUSION IDENTIFIED**

COMMENTS: A panel of genes involved in oncogenic fusions have been screened across their most commonly described fusion breakpoints using total RNA extracted from this patient's pathology sample.

There was no evidence for the presence of a fusion transcript involving any of these genes, including NTRK1, NTRK2, NTRK3 or FGFR2, in this patient's pathology sample.

NTRK/ FGFR

RESULTS:

NAME (DoB)	SAMPLE SOURCE (PATH LAB No.)	RESULT
[redacted]	TUMOUR ([redacted]18 A2)	**NO EVIDENCE OF MSI (Microsatellite Stable – MSS)[1]**

COMMENTS: DNA isolated from tumour tissue from this patient has been analysed for five mononucleotide repeat markers. No normal tissue DNA sample was available for comparison.

There was no evidence for replication errors with any of the mononucleotide markers successfully analysed (NR-21, BAT-26, BAT-25, NR-24 & MONO-27).

MSI

RESULTS:

NAME (DoB)	PATH LAB REF NO.	RESULT
[redacted]	M[redacted]-18 A2	**IDH1 c.394C>A p.(Arg132Ser)**

COMMENTS: DNA extracted from this patient's pathology sample was adequate for somatic NGS mutation analysis, with a mean UMI depth of 109x achieved for the overall target enrichment.

The IDH1 c.394C>A p.(Arg132Ser) mutation was present in this patient's pathology sample (approximate mutant allele frequency was 52% of reads). This mutation has been reported in a range of different tumour types including intrahepatic cholangiocarcinoma (COSMIC ID: COSM28748).

IDH1

Case study 1

5 months; later progression of liver and lung metastasis

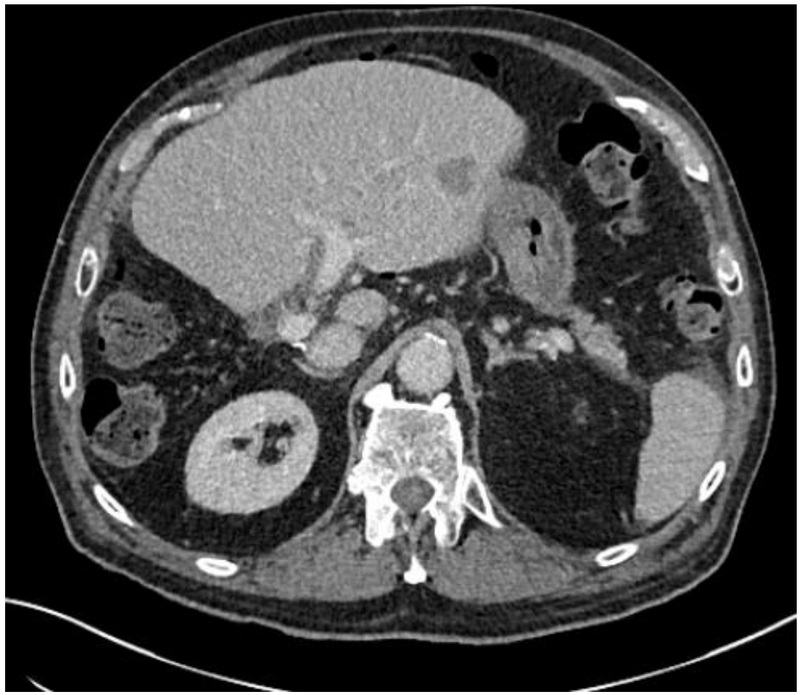
Commences 1st line chemotherapy with cisplatin and gemcitabine with 25% dose reduction

After 2 cycles of treated admitted locally with constipation and abdo pain

Diverticular perforation, some response in liver lesions

Managed conservatively

Chemotherapy stopped

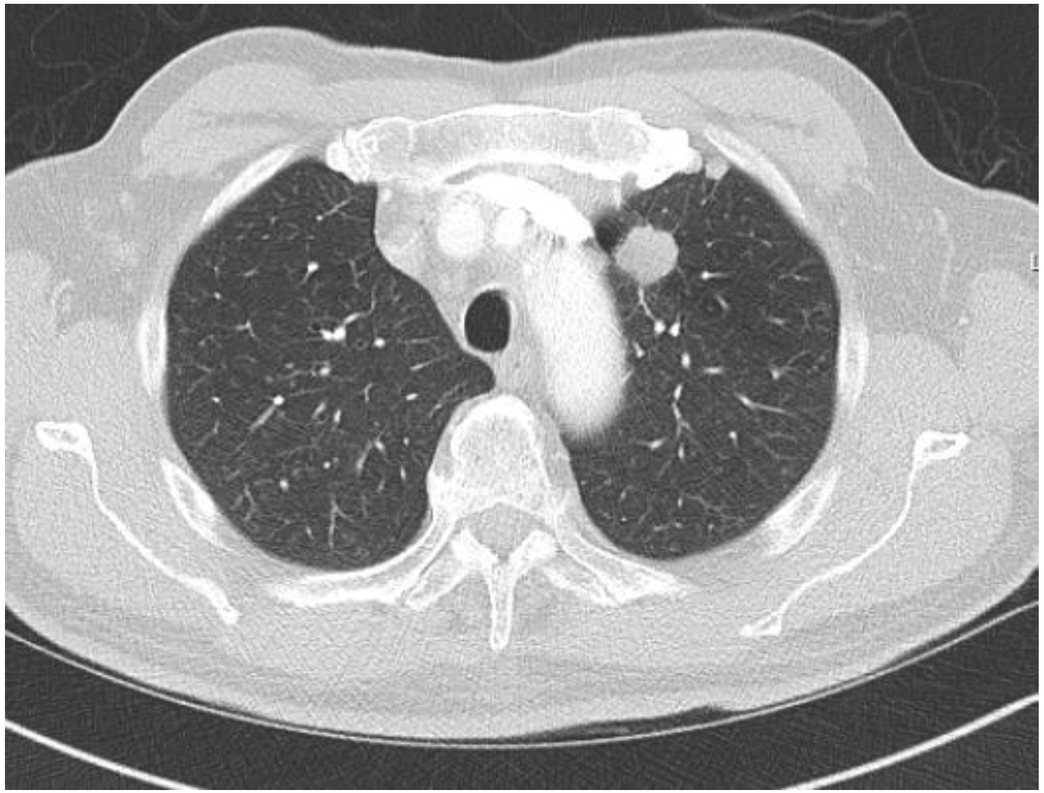


Case study 1

3 months later

CT progression of disease

Commenced **Ivosidenib**



Patient now 87

Had 8 months of ivosidenib

Stable disease

Good QofL

Enjoying frequent holidays.

Learning Objectives

- Understand current pathways ☑
- Discuss why molecular testing is important and how it impacts treatment options ☑
- Establish the role of the genomics champion

Role of genomic champion

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- Increasing the awareness of molecular testing within HPB cancers and promoting personalise care.
- Educating colleagues on the tissue requirements for molecular testing (supporting educational material will be provided for distribution to team members obtaining diagnostic biopsies).
- Requesting molecular profiling from the GLH for patients whose pathology confirms HPB cancer.
- Training other CNS in your area to requesting molecular profiling.

Learning Objectives

- Understand current pathways ☑
- Discuss why molecular testing is important and how it impacts treatment options ☑
- Establish the role of the genomics champion ☑
- Learn how to request molecular testing

Requesting molecular profiling

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Patient presents at GP/A&E with symptoms

Imaging carried out

Discussed at MDT

If suspicious for cancer, FNA/FNB carried out

These steps can be carried out in opposite order

If cancer is confirmed, patient is referred into medical oncology at the Christie. Molecular testing requested

Patient begins first line chemotherapy

How to request molecular testing

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Patient identified as requiring genomic testing

Request completed and sent to pathology lab holding the sample

Pathology lab prepares sample and sends with request to GLH in Manchester

GLH receives sample and request form and carries out testing

Result returned to pathology lab who then contact referrer

Genomic champion

Requesting somatic testing

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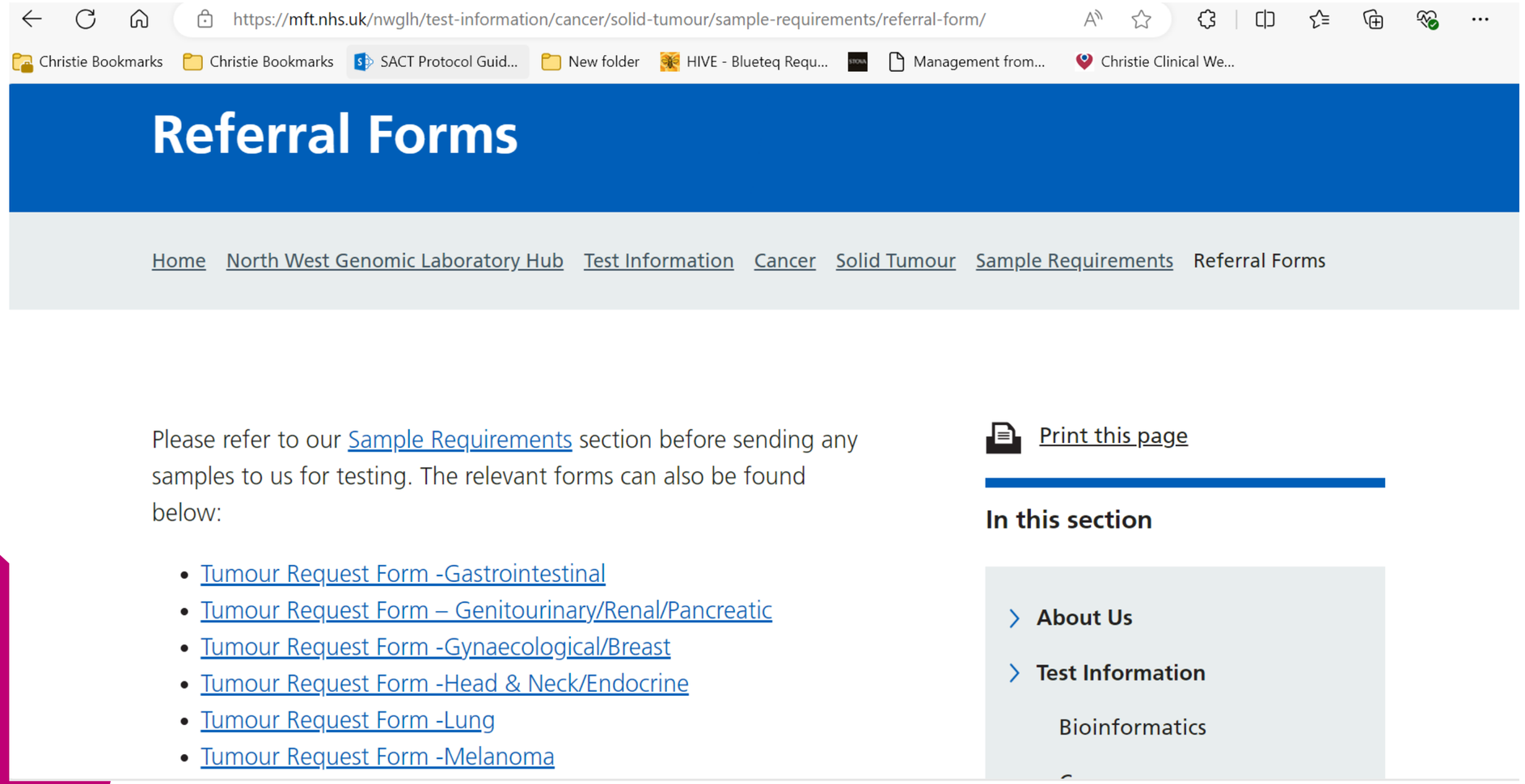

https://mft.nhs.uk/nwglh/test-information/cancer/solid-tumour/sample-requirements/referral-form/

Complete request

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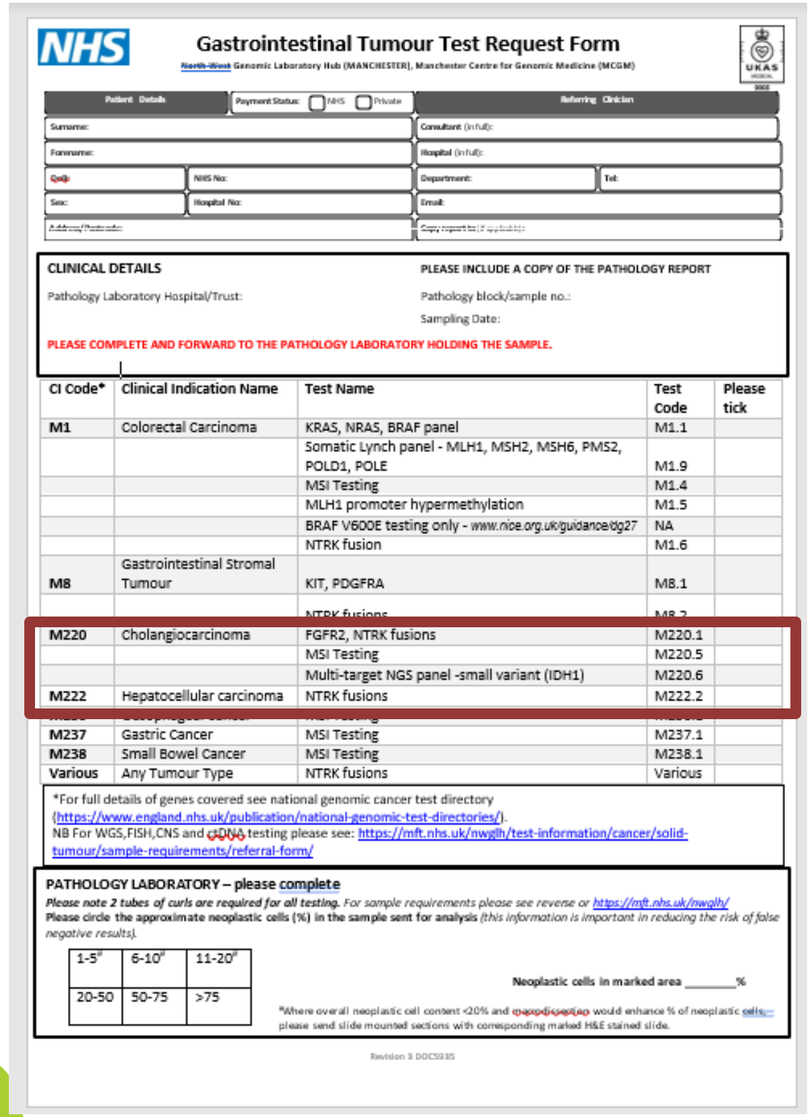


NHS

Gastrointestinal Tumour Test Request Form

North-West Genomic Laboratory Hub (MANCHESTER), Manchester Centre for Genomic Medicine (MCGM)

UKAS MEDICAL 9003

Patient Details	Payment Status: NHS Private	Referring Clinician
Surname:		Consultant (in full):
Forename:		Hospital (in full):
DoB	NHS No:	Department: Tel:
Sex:	Hospital No:	Email:
Address (Postcode):		Copy report to (if applicable):

CLINICAL DETAILS

Pathology Laboratory Hospital/Trust:

PLEASE INCLUDE A COPY OF THE PATHOLOGY REPORT

Pathology block/sample no.:

Sampling Date:

PLEASE COMPLETE AND FORWARD TO THE PATHOLOGY LABORATORY HOLDING THE SAMPLE.

CI Code*	Clinical Indication Name	Test Name	Test Code	Please tick
M1	Colorectal Carcinoma	KRAS, NRAS, BRAF panel	M1.1	
		Somatic Lynch panel - MLH1, MSH2, MSH6, PMS2, POLD1, POLE	M1.9	
		MSI Testing	M1.4	
		MLH1 promoter hypermethylation	M1.5	
		BRAF V600E testing only - www.nice.org.uk/guidance/dg27	NA	
		NTRK fusion	M1.6	
M8	Gastrointestinal Stromal Tumour	KIT, PDGFRA	M8.1	
		NTRK fusions	M8.2	
M220	Cholangiocarcinoma	FGFR2, NTRK fusions	M220.1	
		MSI Testing	M220.5	
		Multi-target NGS panel -small variant (IDH1)	M220.6	
M222	Hepatocellular carcinoma	NTRK fusions	M222.2	
M237	Gastric Cancer	MSI Testing	M237.1	
M238	Small Bowel Cancer	MSI Testing	M238.1	
Various	Any Tumour Type	NTRK fusions	Various	

*For full details of genes covered see national genomic cancer test directory (https://www.england.nhs.uk/publication/national-genomic-test-directories/).
NB For WGS,FISH,CNS and ~~cDNA~~ testing please see: https://mft.nhs.uk/nwglh/test-information/cancer/solid-tumour/sample-requirements/referral-form/

PATHOLOGY LABORATORY – please complete

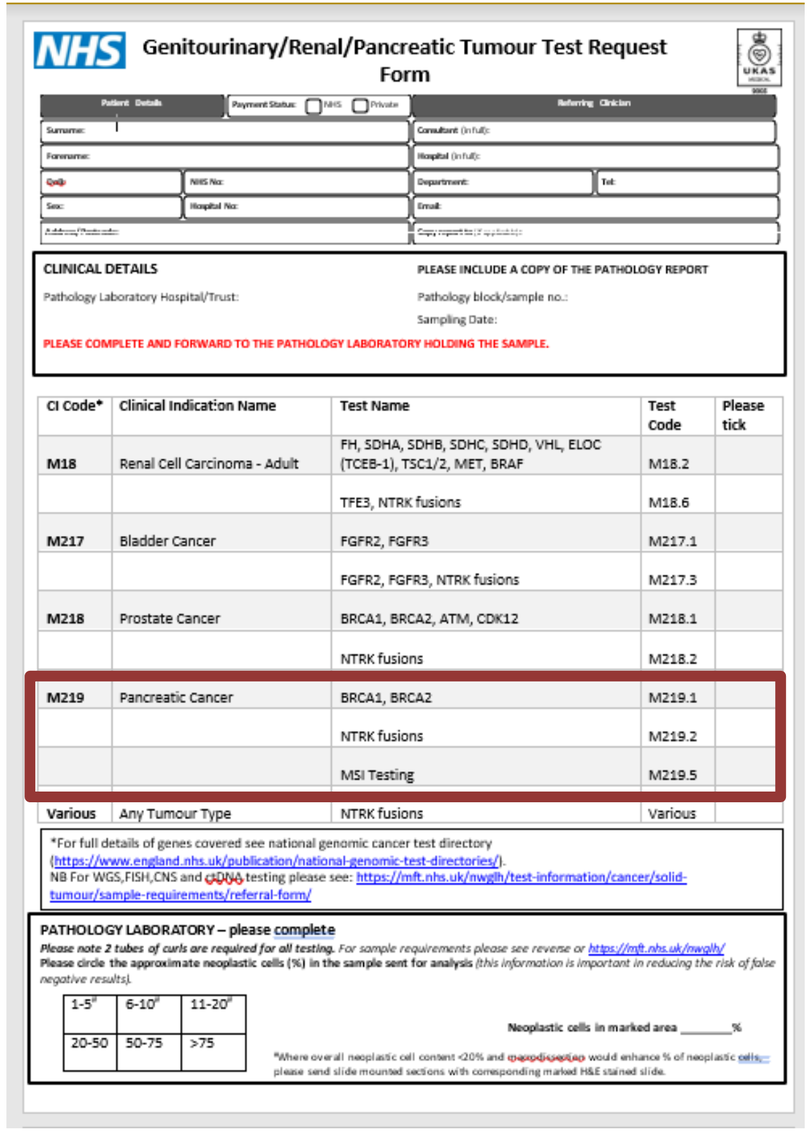
Please note 2 tubes of curls are required for all testing. *For sample requirements please see reverse or https://mft.nhs.uk/nwglh/*
Please circle the approximate neoplastic cells (%) in the sample sent for analysis *(this information is important in reducing the risk of false negative results).*

1-5#	6-10#	11-20#
20-50	50-75	>75

Neoplastic cells in marked area _____%

*Where overall neoplastic cell content <20% and ~~macrodissection~~ would enhance % of neoplastic cells, please send slide mounted sections with corresponding marked H&E stained slide.

Revision 3 DOC5935



NHS

Genitourinary/Renal/Pancreatic Tumour Test Request Form

UKAS MEDICAL 9003

Patient Details	Payment Status: NHS Private	Referring Clinician
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Forename:		Hospital (in full):
DoB	NHS No:	Department: Tel:
Sex:	Hospital No:	Email:
Address (Postcode):		Copy report to (if applicable):

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PLEASE INCLUDE A COPY OF THE PATHOLOGY REPORT

Pathology block/sample no.:

Sampling Date:

PLEASE COMPLETE AND FORWARD TO THE PATHOLOGY LABORATORY HOLDING THE SAMPLE.

CI Code*	Clinical Indication Name	Test Name	Test Code	Please tick
M18	Renal Cell Carcinoma - Adult	FH, SDHA, SDHB, SDHC, SDHD, VHL, ELOC (TCEB-1), TSC1/2, MET, BRAF	M18.2	
		TFE3, NTRK fusions	M18.6	
M217	Bladder Cancer	FGFR2, FGFR3	M217.1	
		FGFR2, FGFR3, NTRK fusions	M217.3	
M218	Prostate Cancer	BRCA1, BRCA2, ATM, CDK12	M218.1	
		NTRK fusions	M218.2	
M219	Pancreatic Cancer	BRCA1, BRCA2	M219.1	
		NTRK fusions	M219.2	
		MSI Testing	M219.5	
Various	Any Tumour Type	NTRK fusions	Various	

*For full details of genes covered see national genomic cancer test directory (https://www.england.nhs.uk/publication/national-genomic-test-directories/).
NB For WGS,FISH,CNS and ~~cDNA~~ testing please see: https://mft.nhs.uk/nwglh/test-information/cancer/solid-tumour/sample-requirements/referral-form/

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NHS

Gastrointestinal Tumour Test Request Form

North West Genomic Laboratory Hub (MANCHESTER), Manchester Centre for Genomic Medicine (MCGM)

UKAS MEDICAL 9865

Patient Details	Payment Status: ☐ NHS ☐ Private	Referring Clinician
Surname:		Consultant (in full):
Forename:		Hospital (in full):
DoB:	NHS No:	Department: / Tel:
Sex:	Hospital No:	Email:
Address/Postcode:		Copy report to (if applicable):

CLINICAL DETAILS

Pathology Laboratory Hospital/Trust:

PLEASE INCLUDE A COPY OF THE PATHOLOGY REPORT

Pathology block/sample no.:

Sampling Date:

PLEASE COMPLETE AND FORWARD TO THE PATHOLOGY LABORATORY HOLDING THE SAMPLE.

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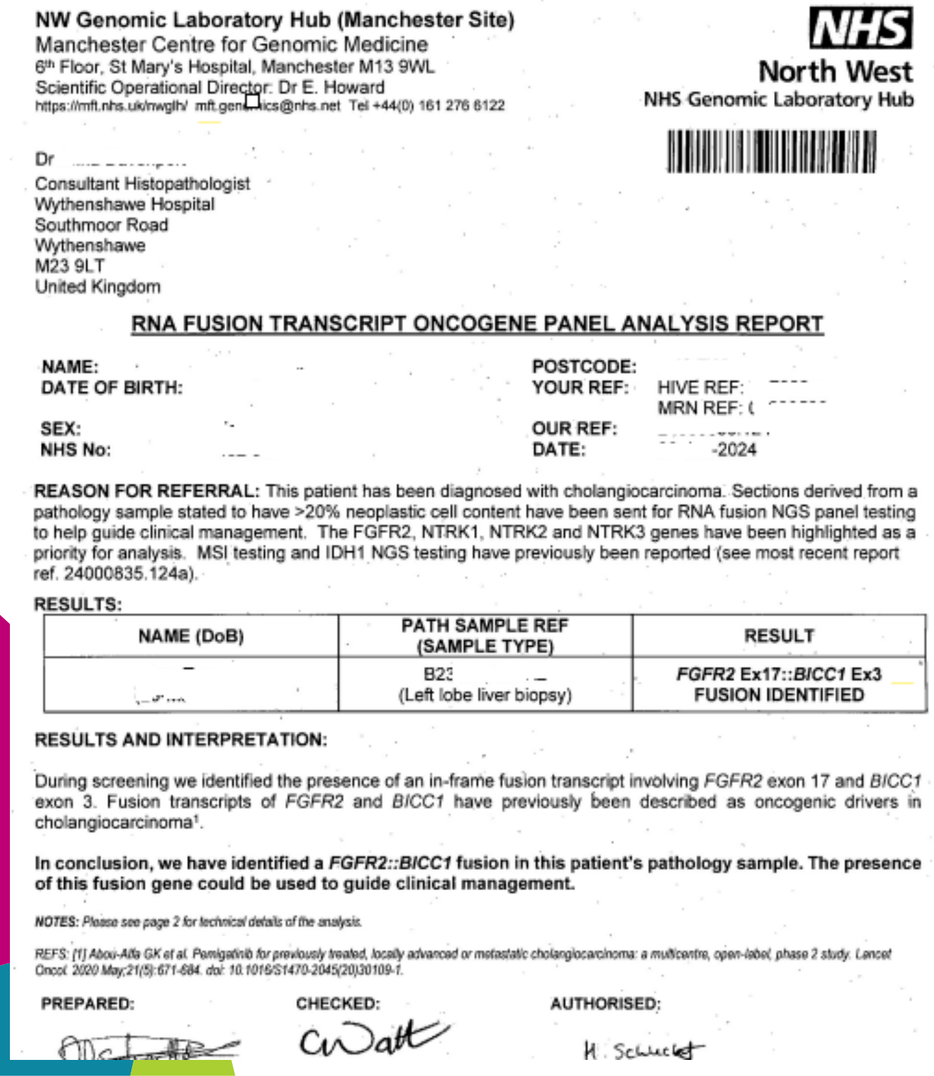
CI Code*	Clinical Indication Name	Test Name	Test Code	Please tick
M1	Colorectal Carcinoma	KRAS, NRAS, BRAF panel	M1.1	
		Somatic Lynch panel - MLH1, MSH2, MSH6, PMS2, POLD1, POLE	M1.9	
		MSI Testing	M1.4	
		MLH1 promoter hypermethylation	M1.5	
		BRAF V600E testing only - *www.nice.org.uk/guidance/dg27*	NA	
		NTRK fusion	M1.6	
M8	Gastrointestinal Stromal Tumour	KIT, PDGFRA	M8.1	
		NTRK fusions	M8.2	
M220	Cholangiocarcinoma	FGFR2, NTRK fusions	M220.1	x
		MSI Testing	M220.5	x
		Multi-target NGS panel -small variant (IDH1)	M220.6	x
M222	Hepatocellular carcinoma	NTRK fusions	M222.2	
M236	Oesophageal Cancer	MSI Testing	M236.1	
M237	Gastric Cancer	MSI Testing	M237.1	
M238	Small Bowel Cancer	MSI Testing	M238.1	
Various	Any Tumour Type	NTRK fusions	Various	

Send to pathology lab holding the sample

Histopathology lab	Email address
NCA	pennineacutehistosecs@nca.nhs.uk;
Manchester Royal Infirmary	molecular.workstream@mft.nhs.uk
Salford Royal	scmhisto@nca.nhs.uk;
Stepping Hill – Stockport	Cellular.Pathology@stockport.nhs.uk;
Wythenshawe	mft.wythenshawe.histosecs@nhs.net;
Bolton	histopathology.medicalsecretary@boltonft.nhs.uk;
The Christie	the-christie.histology@nhs.net

Genomic report

Greater Manchester Cancer Alliance



NW Genomic Laboratory Hub (Manchester Site)
Manchester Centre for Genomic Medicine
6th Floor, St Mary's Hospital, Manchester M13 9WL
Scientific Operational Director: Dr E. Howard
https://mft.nhs.uk/nwglh/ mft.genomics@nhs.net Tel +44(0) 161 276 6122

NHS North West
NHS Genomic Laboratory Hub

Dr
Consultant Histopathologist
Wythenshawe Hospital
Southmoor Road
Wythenshawe
M23 9LT
United Kingdom

RNA FUSION TRANSCRIPT ONCOGENE PANEL ANALYSIS REPORT

NAME:
DATE OF BIRTH:
POSTCODE:
YOUR REF: HIVE REF:
MRN REF:
SEX:
NHS No:
OUR REF:
DATE: -2024

REASON FOR REFERRAL: This patient has been diagnosed with cholangiocarcinoma. Sections derived from a pathology sample stated to have >20% neoplastic cell content have been sent for RNA fusion NGS panel testing to help guide clinical management. The FGFR2, NTRK1, NTRK2 and NTRK3 genes have been highlighted as a priority for analysis. MSI testing and IDH1 NGS testing have previously been reported (see most recent report ref. 24000835.124a).

RESULTS:

NAME (DoB)	PATH SAMPLE REF (SAMPLE TYPE)	RESULT
–	B23 – (Left lobe liver biopsy)	***FGFR2* Ex17::*BICC1* Ex3 FUSION IDENTIFIED**

RESULTS AND INTERPRETATION:

During screening we identified the presence of an in-frame fusion transcript involving *FGFR2* exon 17 and *BICC1* exon 3. Fusion transcripts of *FGFR2* and *BICC1* have previously been described as oncogenic drivers in cholangiocarcinoma[1].

In conclusion, we have identified a *FGFR2::BICC1* fusion in this patient's pathology sample. The presence of this fusion gene could be used to guide clinical management.

NOTES: Please see page 2 for technical details of the analysis.

REFS: [1] Abou-Alfa GK et al. Pemigatinib for previously treated, locally advanced or metastatic cholangiocarcinoma: a multicentre, open-label, phase 2 study. Lancet Oncol. 2020 May;21(5):671-684. doi: 10.1016/S1470-2045(20)30109-1.

PREPARED: **CHECKED:** **AUTHORISED:**

Forward ALL reports to oncology
the-christie.hpbnetmedoncadmin@nhs.net

And named consultant

Learning Objectives

Greater Manchester Cancer Alliance

- Understand current pathways ☑
- Discuss why molecular testing is important and how it impacts treatment options ☑
- Establish the role of the genomics champion ☑
- Learn how to request molecular testing ☑
- Understand reflex testing pathway

Reflex molecular testing for biliary tract cancers

Biliary tract cancers (BTC), including cholangiocarcinoma and gallbladder cancer, are rare, aggressive malignancies, that are often diagnosed at an advanced, inoperable stage. Palliative chemotherapy remains the backbone of treatment for patients with advanced BTC, but has limited efficacy, and the prognosis is poor. Less than 20% of patients presenting with advanced BTC survive 12 months (SEER data).

Recent advances in understanding the genetic landscape of BTC have resulted in the development of new targeted therapies. Identification of actionable molecular alterations, such as *FGFR2* fusions or *IDH1* mutations, now allow for the use of targeted therapies that can expand treatment options and improve outcomes for a sub-set of patients.

High-quality diagnostic biopsies remain critical, not only for histological diagnosis, but also to enable comprehensive molecular testing and potentially access to targeted therapies.

Radiologists/Endoscopists/Surgeons

Biliary tract cancer suspected by Radiologists/Endoscopist/Surgeons carrying out a biopsy

↓

FNB biopsy performed

(cytology brushings alone inadequate for molecular testing)

↓

Comment added to the request card: **'Suspected biliary tract cancer, please request *FGFR2* fusion/*IDH1* mutation/*NTRK* fusion/MSI testing testing from GLH'**

Pathologists

BTC confirmed by pathology

↓

FGFR2 fusion/ IDH1 mutation/ NTRK fusion/MSI panel testing requested by pathology

↓

Results of genomic testing will be returned to the pathology department

↓

Results must be forwarded to oncologist and surgeon/referrer

- If BTC is confirmed, the following should be requested: FGFR2 fusion/IDH1 mutation/NTRK fusion/MSI should be requested. The request form can be found on the NW GLH website by clicking through the following: **Documents and Forms – Test request forms – Cancer Solid Tumour – Tumour Request Form**
- Sample requirements can be found on the request form. Once prepared, the sample and form should be sent to the NW GLH in Manchester (address can be found on the request form)
- The results will be returned to the pathology lab via email. These should then be forwarded to the referrer (contact details should be available on the referral card), and The Christie oncology department: the-christie.hpbnetmedoncadmin@nhs.net

Simran Chander, Personalised Care Manager
Victoria Foy, Medical Oncology Consultant

NHS Greater Manchester Cancer Alliance

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Questions?