NOVARTIS

PATHways UK 2021

Understanding Current Challenges in Oncology Molecular Pathways in the UK

This market research study is organised and funded by Novartis Pharmaceuticals UK Ltd

Introduction

The purpose of this nationwide survey is to gain a better understanding of the current services and challenges for cancer diagnostics in UK pathology laboratories.

With recent events impacting the patient oncology diagnostic pathway, including impact of COVID-19 and the centralisation of molecular services to Genomic Laboratory Hubs, this study is designed to capture key points on current and evolving molecular pathology services and pathways with a specific focus on molecular testing in Melanoma, Breast and Lung Cancer.

In particular, we aim to highlight the barriers and challenges that may exist for pathology laboratories in providing, and areas requiring further support that may help enable, a diagnostic infrastructure supporting optimal patient management.

Please note, the results are anonymised and will be aggregated together with the responses of other participants. Your responses will therefore not be attributable to you as an individual or center and you will not be identifiable.

Respondent Profile

1. **Responder ID (to be completed by Novartis Associate)** .....

2. **Where in the UK is your Lab?**

England ☐ Scotland ☐ Wales ☐ Northern Ireland ☐

3. **How would you categorise your hospital?**

District General ☐ Regional Centre ☐ Other ☐

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4. What region does your lab cover for diagnosis and management of cancer samples?

Local only ☐ Referral network ☐

Estimated populations size: .....

5. Which is your regional GLH or genomics centre?

Central & South GLH ☐ East GLH ☐ North West GLH ☐ North Thames GLH ☐ South East GLH ☐ South West GLH ☐ North East & Yorkshire GLH ☐

Scottish Genetics Consortium: Glasgow ☐ Edinburgh ☐ Aberdeen ☐ Dundee ☐

All Wales Medical Genomics Service (Cardiff) ☐

Precision Medicine Centre (Belfast) ☐

6. Which technologies do you currently use at your lab?

IHC ☐ FISH ☐ RT-PCR ☐ Sanger Sequencing ☐ NGS ☐

Other .....

Testing for Specific Cancers of Interest

7. Can you provide an estimate of the number of samples you receive per month for each of the following:

Breast ☐ Lung ☐ Melanoma Skin ☐ Other Cancers ☐

8. For breast cancer, what is the current status of the following tests within your lab?

Test	Reflex at diagnosis Y/N/On request	Testing at progression/ relapse/ other post Dx timepoints Reflex/On request/No	Performed by pathology lab Y/N	Moved to GLH/ Genomic centre Y/N	Moving to GLH/ Genomic hubs Y*/N *include timeframe if known	Current Average Turnaround time (calendar days)	Additional Notes
IHC							
HR							
HER2							
PGR							
PD-L1							
NTRKfus							
FISH							
HER2							
NTRKfus							
RT-PCR							
PIK3CA							

BRCA1/2							
NTRKfus							
NGS							
PIK3CA							
HER2							
NTRKfus							
BRCA1/2							
Others							

9. For lung cancer, what is the current status of the following tests within your lab?

Test	Reflex at diagnosis Y/N/On request	Testing at progression/ relapse/ other post Dx timepoints Reflex/On request/No	Performed by pathology lab Y/N	Moved to GLH/ Genomic centre Y/N	Moving to GLH/ Genomic hubs Y*/N *include timeframe if known	Current Average Turnaround time (calendar days)	Additional Notes
IHC							
PD-L1							
ROS1fus							
ALKfus							
BRAF							
NTRKfus							
FISH							
ALKfus							
ROS1fus							
METamp							
HER2amp							
RETfus							
NTRKfus							
RT-PCR							
EGFR							
ROS1fus							
ALKfus							
ALK							
BRAF							
KRAS							
METex14							
HER2							
RETfus							
NTRKfus							
NGS							
EGFR							
ROS1fus							
ALKfus							
BRAF							

KRAS							
METex14							
HER2							
RETfus							
NTRKfus							
Others							

10. For melanoma, what is the current status of the following tests within your lab?

Test	Reflex at diagnosis Y/N/On request	Testing at progression/ relapse/ other post Dx timepoints Reflex/On request/No	Performed by pathology lab Y/N	Moved to GLH/ Genomic centre Y/N	Moving to GLH/ Genomic hubs Y*/N *include timeframe if known	Current Average Turnaround time (receipt of sample to results reported - calendar days)	Additional Notes
IHC							
BRAF							
PD-L1							
Sanger sequencing							
BRAF							
NRAS							
Pyrosequencing							
BRAF							
RT-PCR							
BRAF							
NRAS							
KIT							
NGS							
BRAF							
NRAS							
KIT							
Others							

11. Please answer the following questions regarding your process for managing urgent samples?

a. What is the selection of tests used for the following types of cancer:
   i. Breast Cancer: HR ☐ PGR ☐ HER2 ☐ Other ..... N/A ☐
   ii. Lung Cancer: PD-L1 ☐ EGFR ☐ ALK ☐ BRAF ☐ ROS1 ☐ RET ☐ Other..... N/A ☐
   iii. Melanoma: BRAF ☐ Other..... N/A ☐

b. Are these all performed in house? i.e. at your regional pathology centre. If not, where are they performed?
   Yes ☐ No ☐ :.....

c. For molecular testing, which technology is preferred? (Select one)
   IHC ☐ RT-PCR ☐ Other.....

d. Who is funding this testing?
NHS Trust ☐ GLH ☐ N/A ☐

e. Are samples also sent to GLH for NGS?
Yes ☐ No ☐ N/A ☐

12. What percentage of samples you receive for the following cancers are urgent?

Breast.....

Melanoma.....

Lung.....

13. Please answer the following questions regarding the use of archival tissue:

a. Please describe the process for request of archival tissue: .
.....
.....

b. Describe the specific challenges with archival tissue that may exists for Lung, Breast or Melanoma?.....
.....
.....

c. What is the turnaround times from request to receipt of the tissue? (calendar days)
   i. Breast .....
   ii. Lung .....
   iii. Melanoma .....

d. What are the challenges with archival tissue for genomics at GLH?
Sample quality ☐
Additional resource requirements ☐
Processing issues ☐
Transport ☐
Other .....

14. Please answer the following questions regarding liquid biopsies:

a. Do you currently offer molecular testing of liquid biopsies at your lab?
EGFR only ☐ No ☐

b. Are there any other molecular liquid biopsies performed at your lab? If so, which one(s) and for which cancer types?
No ☐
Yes ☐:.....

c. What do you foresee will be the use of liquid biopsy within the diagnostic pathway?
For all testing ☐
In addition to tissue testing (same targets) ☐
If a suitable tissue sample is not available ☐

Upon progression only ☐
For specific tests only ☐ i.e. .....
For panel testing ☐
Not used ☐

d. What are the challenges with liquid biopsies? .....
.....
.....
.....

15. Are you currently developing any other molecular tests for Lung, Breast or Melanoma?

Please describe .....

Pathway and Logistics

16. What are the biggest difficulties with implementing a new test?

Timelines for implementation ☐

Test development ☐

Test validation ☐

Administration ☐

Funding/Resource allocation ☐

Communication ☐

Other .....

17. Who is your point of contact within clinic?

Respiratory physicians/ Pulmonologists ☐

Surgeon ☐

Oncologist ☐

MDT coordinator ☐

Clinical nurse specialist ☐

Other .....

18. Do you regularly attend MDT?

Yes ☐ No ☐

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19. Do you discuss results at standard MDTs?

Yes ☐ No ☐

20. Do you have a molecular specific MDTs?

Yes ☐ No ☐

21. Who initiates the testing process?

Respiratory physicians/ Pulmonologists ☐

Surgeon ☐

Administrator ☐

Pathologist ☐

Clinical Scientist (genomics) ☐

Oncologist ☐

Other .....

22. How do you communicate with clinicians? i.e. regarding how to access testing or to inform them of the availability of a new test?

Email ☐

Webpage ☐

Hospital Newsletter ☐

MDT meeting ☐

Other .....

23. On your reports, is clinical interpretation of the molecular results provided with reference to published disease area management recommendations, and available targeted therapies?

No ☐

Yes ☐

Reference to published therapy area guidelines only ☐

Reference to available targeted therapies only ☐

Other .....

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Recent Changes

24. What impact has COVID-19 had on your current services?

Minimal or no impact ☐ Medium impact ☐ High impact ☐

Please describe if medium or high impact…….....……..

25. What impact has the roll out of the GMS and GLH had on your current services (positive and/or negative)?

Minimal or no impact ☐ Medium impact ☐ High impact ☐ N/A ☐

Please describe .....……..

26. What impact will the roll out of the GMS and GLH had on your future services (positive and/or negative)??

Minimal or no impact ☐ Medium impact ☐ High impact ☐ N/A ☐

Please describe ….....……..

27. Where do you see the role of regional pathology centres in the optimal delivery of the GMS?

Sample preparation ☐

Test assignment (reflexive) ☐

Conducting testing: all ☐ cellular ☐ salvage ☐ urgent or first line testing ☐

Data analysis ☐

Report creation ☐

Education/training ☐

Other .....

28. How do you currently work with your GLH? i.e. access to tissue, sample preparation, salvage/urgent testing, preparation of reports, etc.

Please describe …….....
.....

N/A ☐

Barriers and Support

29. What do you see as the current barriers for optimal delivery of the GMS? Tick the relevant boxes.

Barrier	Mini or no impact	Med Imp	High Im t	Not applicable
Sample Quality				
Transportation				
Ordering GLH tests				
Admin				
Testing options/capabilities				
Data analysis/ bioinformatics				
IT requirements/ compatibility				
Reporting				
Education/training				
Resource/Capacity				
Funding				
Other.....				

30. Do you have other concerns regarding the delivery of this service?

Yes ☐ No ☐

If yes please describe .....
.....

31. What additional resources are required at local pathology labs to support optimal delivery of this service?

Please describe .....
.....

32. What educational support is needed for pathologists from different sites?

Topics	Regional pathology centres	DGH pathology labs
New treatment trial results		
Optimal reporting		
Guideline reviews/updates		
Understanding the new molecular testing pathway		
Best practice sharing across lab		
Cross-functional education with clinicians		
Other.....		

33. What educational support is needed for HCPs?

Topics	Surgeons	CNS	Clinicians
Interpreting reports/results			
Overview of different types of tests			
Tissue requirements			
Patient information – testing and results			
Other.....			

34. What type of education is preferred?

Digital education ☐

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Paper education ☐

HCP Portal/websites ☐

Educational Meetings: virtual ☐ in person ☐

Preceptorships ☐

Other .....

Thank you for taking the time to complete the survey

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