Molecular Pathology Consortium / Evaluation Panel

Anca Oniscu

National Clinical Lead Molecular Pathology

Scottish Pathology Network

Overview

- Molecular Pathology testing in Scotland
- MPEP / MPC remit and roles
- Challenges and opportunities

NHS National Services Scotland

Scottish Pathology Network

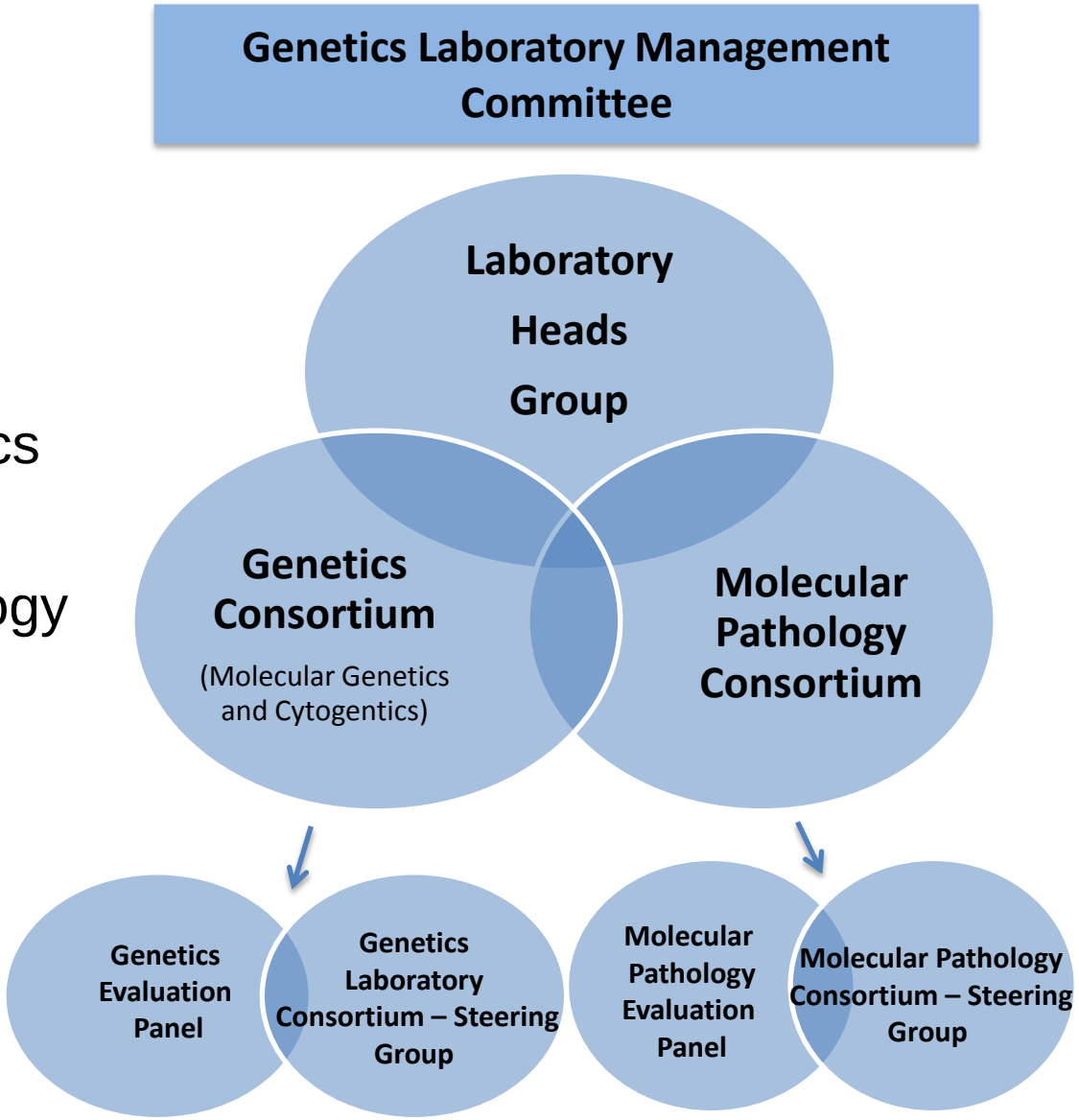
Overview of Service in Scotland

National designation:

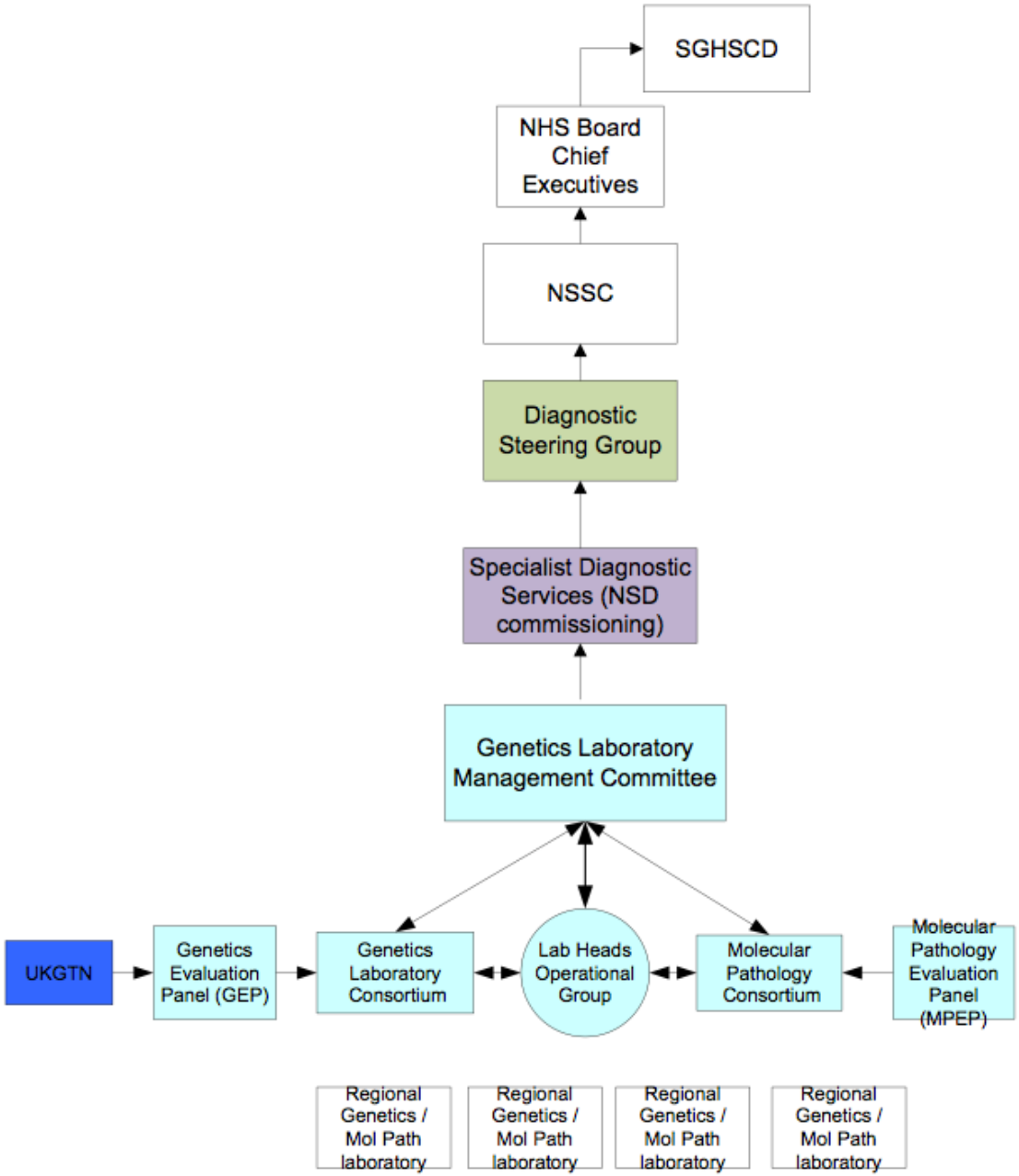
1989 – Molecular Genetics

2009 – Cytogenetics

2013 – Molecular Pathology



NHS National Services Scotland



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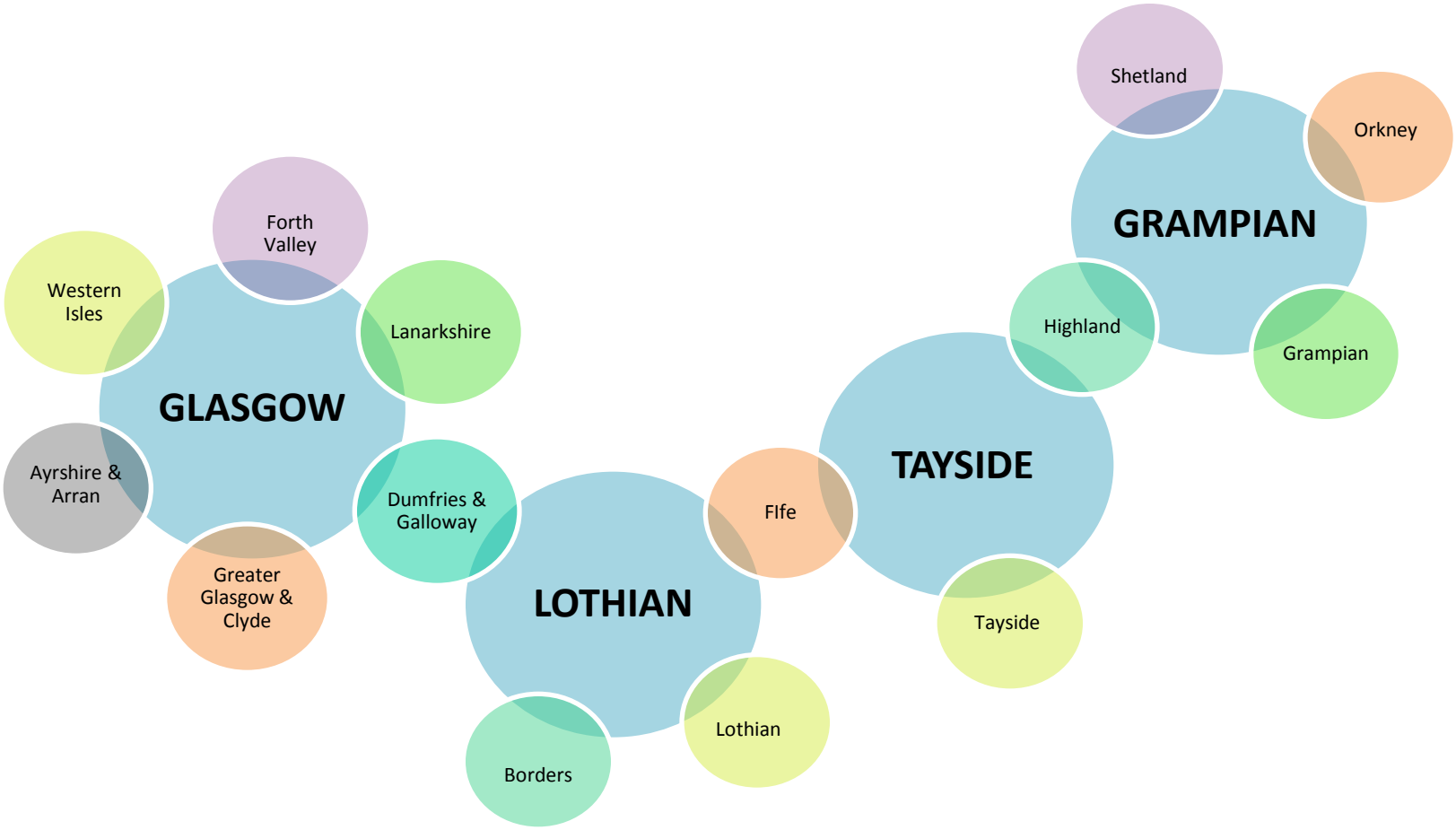
Scottish Regional Genetic Centres

NHS National Services Scotland



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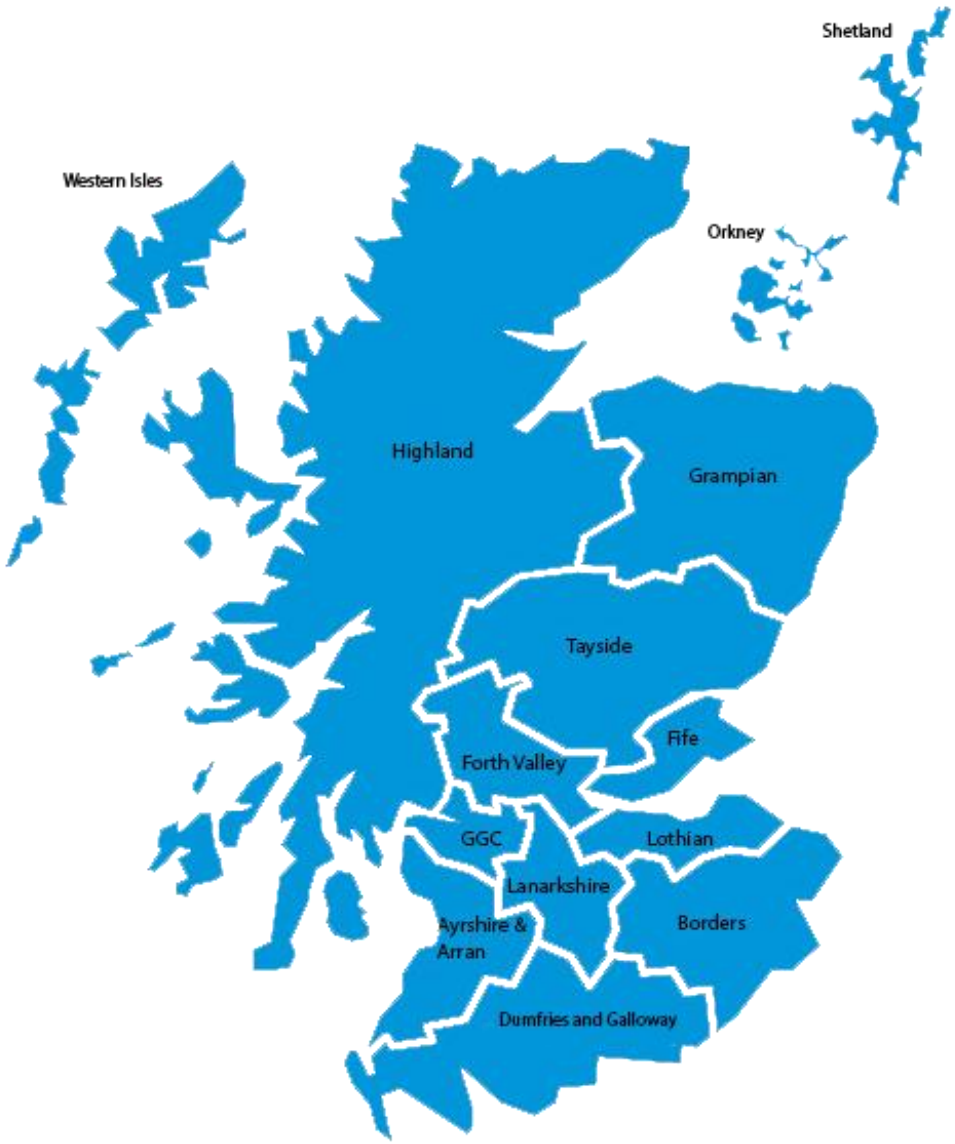
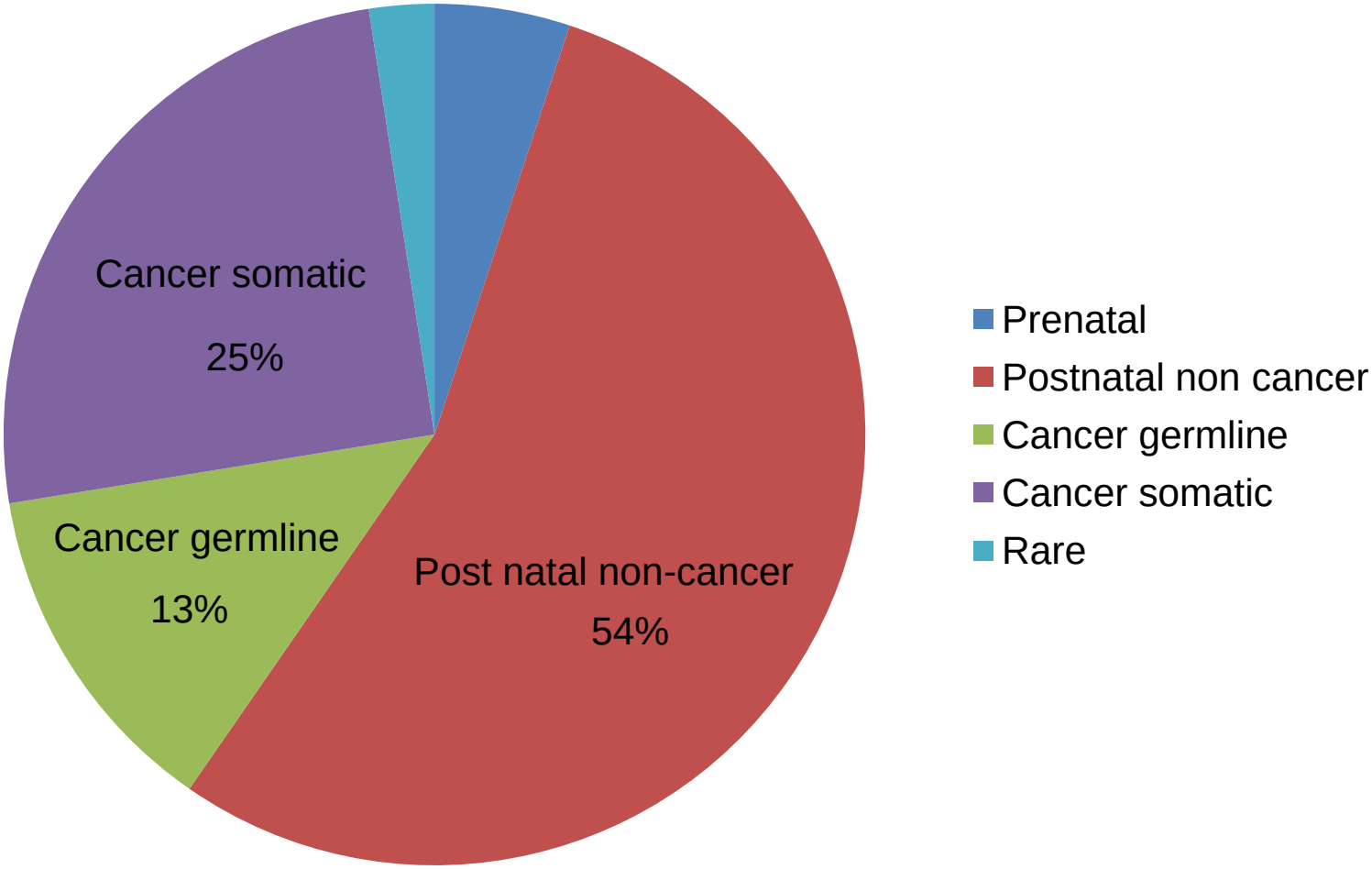
Populations of Scotland



Population Figures 2014/15	
Ayrshire and Arran	371,110
Borders	114,030
Dumfries and Galloway	149,940
Fife	367,260
Forth Valley	300,410
Grampian	584,240
Greater Glasgow & Clyde	1,142,580
Highland	320,760
Lanarkshire	653,310
Lothian	858,090
Orkney Islands	21,590
Shetland Islands	23,230
Tayside	413,800
Western Isles	27,250
	5,347,600

Workload Activity



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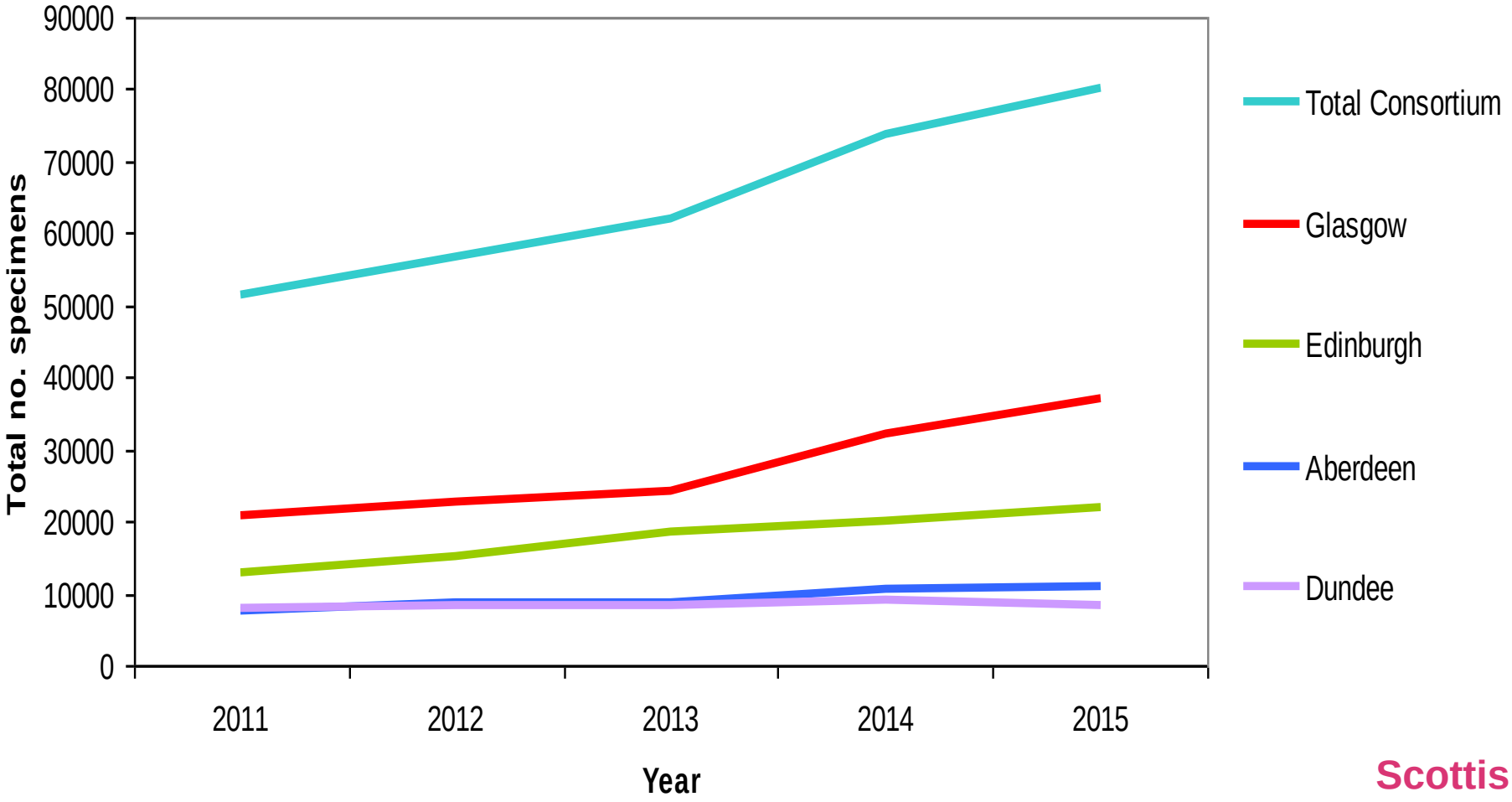
Samples received 2011-2015



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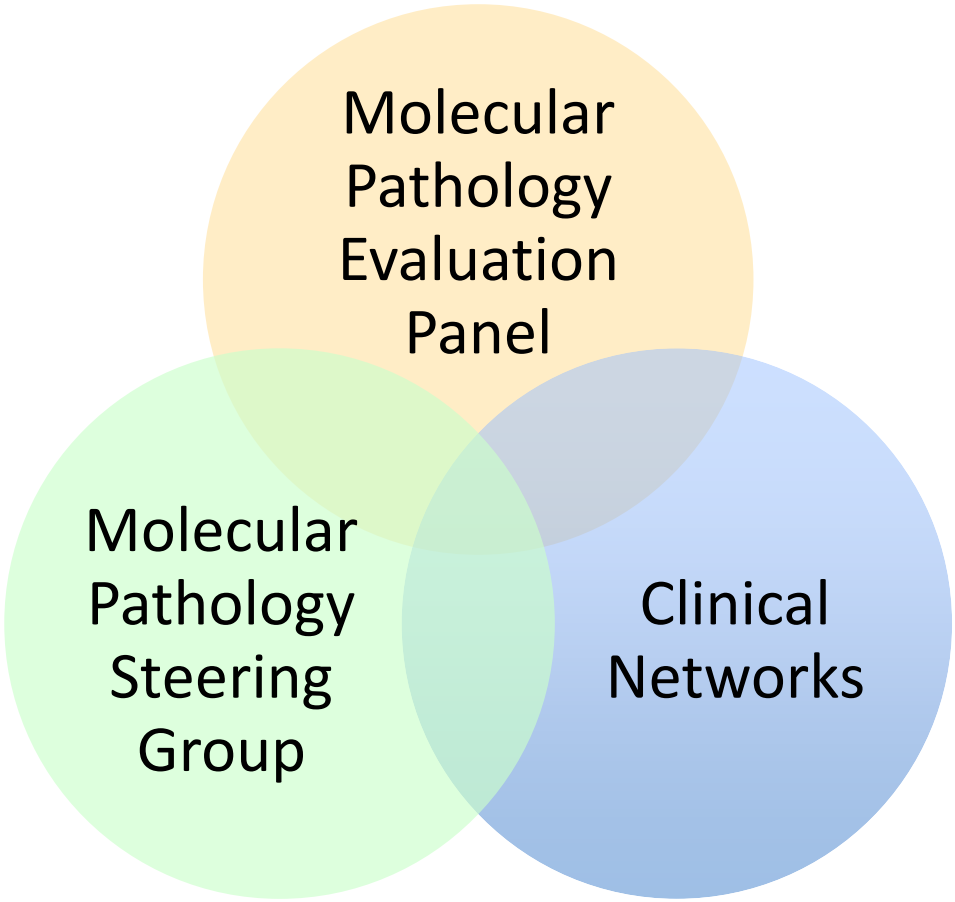
Molecular Pathology Consortium - 2013

NHS National Services Scotland



'Framework for Decision Making for tests in the Scottish Molecular Pathology Service'

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Molecular Pathology tests

- 90% - Biomarker predictive testing – SMC
- Diagnostic accuracy
- Prognosis
- Screening for germline disease
- Disease monitoring

Lung & CRC cancer, melanomas, brain tumours, sarcomas, haematological malignancy.

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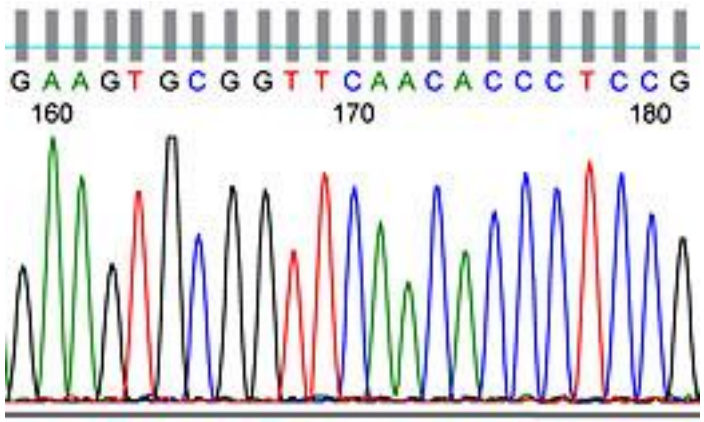
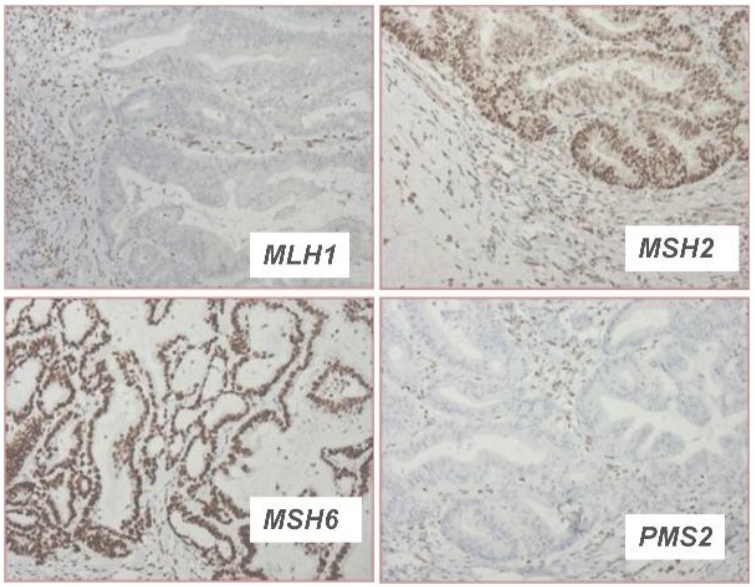
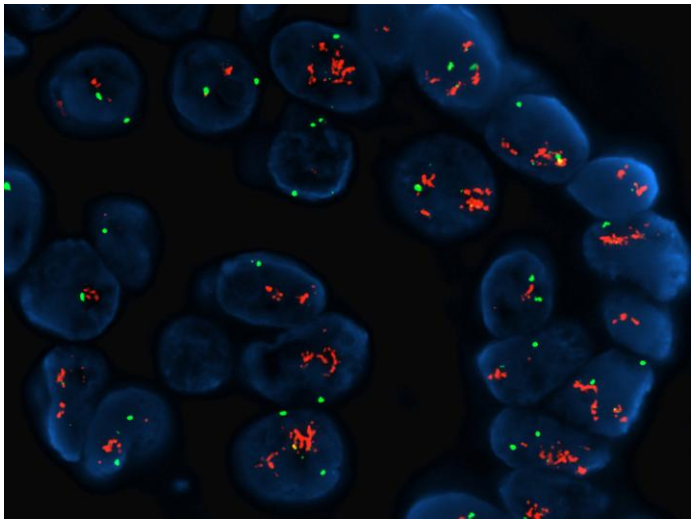


Sequencing



Protein expression



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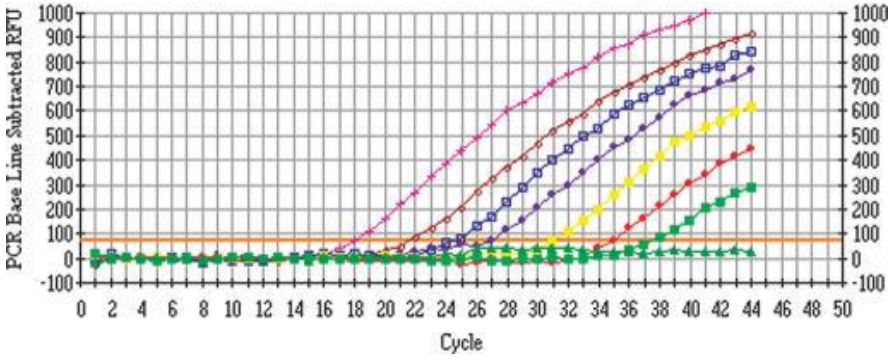

Real-time PCR

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Molecular Pathology Evaluation Panel

- A forum for all users to provide evidence on the clinical needs and priorities for molecular pathology testing

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Remit

- Discuss proposals for developments
- Appraise evidence on test submissions
- Make recommendations to the Molecular Pathology Steering Group on the clinical utility of the test, analytical and clinical validity of the test to be provided in Scotland
- Evaluate current practice and develop pathways to ensure a clinical cost-effective approach
- Share good practice to improve quality and efficiency of the clinical services

Role	Name	Title and who representing
Chair	Prof Nick Reed	Consultant Clinical Oncologist
Pathology x 2	Prof Keith Kerr Dr Craig Dick	Consultant Pathologist, NHS Grampian Consultant Pathologist, NHS GG&C
Haematology x 2	Dr Keith Gelly Dr Mark Drummond	Consultant Haematologist, NHS Tayside Consultant Haematologist, NHS GG&C
Oncology x2	Dr Rob Jones Dr Allan Price	Medical Oncologist, West of Scotland Consultant Oncologist, East of Scotland
Scientist from across the four providing Boards x4	Dr David Baty Dr David Stevenson Kathy Walsh Dr Paul Westwood	Scientist, NHS Tayside Scientist, NHS Grampian Scientist, NHS Lothian Scientist, NHS GGC
Any clinical user submitting a proposal can attend to present/discuss		
Committee Support Team		
Director of NSD	Fiona Murphy	
Medical Advisor, NSD	Dr Craig Wheelans	
Programme Associate Director	Peter Croan	
Programme Manager	Karina O'Rourke	
Programme Support Officer	Louise Mathew	

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Molecular Pathology Consortium Steering Group

NHS National Services Scotland

- Tasked with specific objectives by the Laboratory Management Committee
- Makes recommendations on developments and improvements of molecular pathology services
- Strategic direction for the developments of molecular pathology technologies in NHS Scotland
- Ensures equal access to high quality timely tests
- Shares information, audit performance and good practice
- Pursues opportunities to improve quality and efficient services for molecular pathology

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Role	Name	Title and who representing
Chair	Dr Anca Oniscu	Lead Molecular Pathologist
Scientists from the four providing Boards x4	Dr Norman Pratt Dr Caroline Clark Dr Jennifer Fleming Nicola Williams	NHS Tayside NHS Grampian NHS Lothian NHS GGC
Lead scientist	Dr David Baty	Heads of Laboratories
Chair of the Molecular Pathology Evaluation Panel	Prof Nick Reed	Consultant Clinical Oncologist
Regional Cancer Networks: Management WOSCAN / SCAN / NOSCAN **Clinical** WOSCAN / SCAN /NOSCAN	 Evelyn Thomson Kate MacDonald Dr Fiona Scott Dr Dominic Culligan Dr Les Samuel Dr Russell Petty *(rotating attendance)*	 Regional Manager West of Scotland Cancer Network Network Manager South East Scotland Cancer Network Consultant Haematologist, NHS Lothian, Consultant Haematologist, NHS Grampian Consultant Oncologist, NHS Grampian Chair of Medical Oncology, University of Dundee
Scottish Pathology Network	Dr Elizabeth Mallon Dr Allan Wilson	Consultant Pathologist, Lead Clinician SPAN Lead Biomedical Scientist in Cellular Pathology, Network Scientific Managers SPAN
Lay rep	TBC	
NHS Board Management	TBC	
NSS Director of Healthcare Scientist	Dr David Stirling	Director of Healthcare Science
Committee Support Team		
Director of NSD	Fiona Murphy	
Medical Advisor, NSD	Dr Craig Wheelans	
Programme Associate Director	Peter Croan	
Programme Manager	Karina O'Rourke	
Programme Support Officer	Louise Mathew	

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New test ? What to do ?

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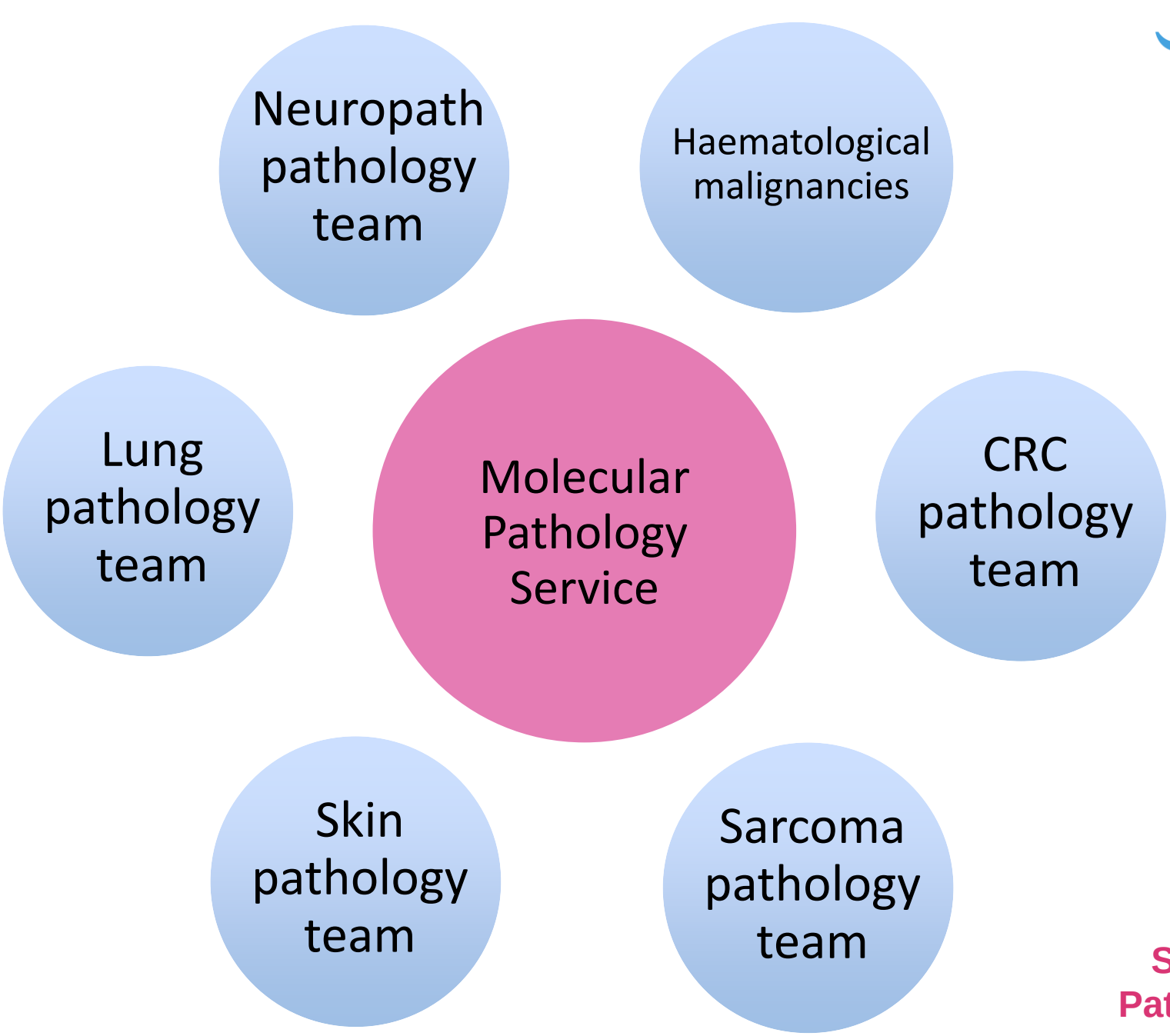

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1. ADMINISTRATIVE DETAILS	
1.1 Date of submission	
1.2 Requesting clinician details (name, address and email)	
1.3 Supporting laboratory details (name, address and email)	
1.4 Type of application	☐ Extension to scope ☐ New test
2. DISORDER/ TESTING INFORMATION	
2.1. Disease/ condition – Provide a brief characteristics of the disease/ condition and prognosis focusing on the affected patient cohort. Please use layman's terms and limit to 200 words.	
2.2 Testing information – Provide details of test required. Include gene name/ testing technology where appropriate. Please use layman's terms and limit to 100 words.	
2.3 Patient cohort – Provide estimated number of patients and tests for Scotland.	
2.4 Patient benefit – Provide details of why this test is required and what the patient benefits are. Please use layman's terms and limit to 200 words.	
3. ADDITIONAL INFORMATION	
Provide additional information that you think may be relevant to the Molecular Pathology Steering Group. Please use layman's terms and limit to 200 words.	

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Invitation to submit the full submission – part 2

- Upon MPC's agreement to proceed with submission and completion of part 2

1. CURRENT PROVISION	
1.1. Are you providing an alternative test for this gene (s)/disease/condition?	☐ Yes ☐ No
If yes, please provide details.	
• Has this test been evaluated by the MPEP?	☐ Yes ☐ No
• How long have you been providing this test?	
• Current annual activity (i.e. number of tests)	
1.2. Is there specialised local clinical/research/laboratory level expertise for this disease?	☐ Yes ☐ No
If yes, please provide details.	
1.3. Are you providing this test for other gene(s)/ disease/condition(s)?	☐ Yes ☐ No
If yes, please give details: • Name(s) of gene(s)/disorder(s) that this test is provided for	
• Has this test been evaluated by the MPEP?	☐ Yes ☐ No
• Current annual activity (i.e. number of tests)	
• Performance in these and relevant EQA schemes	

2. CLINICAL VALIDITY		
Please tick all the relevant purposes of testing. It is helpful when completing the Submission, to consider which of these clinical management areas the test is likely to enhance. These will be considered by the panel in the evaluation of the proposed test. If this test is required to stratify a drug treatment, please cite the relevant SMC submission.		
2.1. Diagnosis	☐ Yes	☐ No
If yes, please provide details: • Can a diagnosis be made for certain by any other method?		
• Will a molecular diagnosis remove the need to do other tests?		
2.2. Treatment	☐ Yes	☐ No
If yes, please give details: • Will a specific molecular diagnosis affect treatment?		
• If this test is required to stratify a drug treatment, please cite the relevant SMC submission.		
2.3. Prognosis & management	☐ Yes	☐ No
If yes, please give detail: • Is there evidence in this disease that a specific molecular sub-type will affect prognosis and management to a significant extent?		
• Will the result significantly affect the lifestyle choices of the patient or the family?		
• Will the additional evidence on prognosis alter subsequent treatment? If so, how?		
2.4. ***Disease monitoring*** *Will molecular diagnosis provide a means to assess disease status in the patient*	☐ Yes	☐ No

3. ANALYTICAL VALIDITY

3.1. Analytical sensitivity and specificity

This should be based on your own laboratory data for the specific test being applied for or the analytical sensitivity and specificity of the method/technique to be used in the case of a test yet to be set up.

3.2. Estimated positive predictive value, clinical sensitivity and negative predictive value of test.

Please identify the information on which this is based (if applicable). In molecular pathology the issue of relevance is the likelihood that a positive test result (e.g. presence of a gene mutation in tumour tissue) will confer resistance / sensitivity to the drug of interest.

3.3. Technical method(s)

Please provide details of the assay(s) proposed.

3.4. Validation process

Has this test been validated for use in your laboratory? If no, please provide details of likely timeframe for validation.

3.5. Mutational spectrum

Please provide details of mutation/ genetic abnormality this test will detect.

4. CLINICAL UTILITY

4.1. Estimated incidence/prevalence of condition in the target population to whom the test applies.

The target population is the group of people that meet the minimum criteria for testing. Please provide references to data and relevant research where possible.

4.2. How will the test add to the management of the patient or alter clinical outcome?

4.3. Please provide a summary of the overall benefits of the test.

4.4. Is there an alternative means of diagnosis or prediction that does not involve molecular diagnosis? If so (and in particular if there is a biochemical test), please state the added advantage of the molecular test.

5. COST EFFECTIVENESS

5.1. Costs of test

The costs should reflect the resources that will be required to undertake the test e.g. staffing, consumables etc.

Price per test	Expected national activity Number	Total cost of testing for national activity
£ _____	Number: _____	£ _____

5.2. Intellectual property Are there intellectual property issues related to this test?	☐ Yes	☐ No
In particular, are there UK licensing requirements for the provision of this test met?	☐ Yes	☐ No
Please provide details of any issues identified.		

5.3. Savings or investment per annum in the diagnostic pathway based on national expected activity, cost of diagnostics avoided and cost of genetic test. Please provide calculations.

5.4. If there are cost savings, please provide these below. List the diagnostic tests/procedures/ treatments that would no longer be required with costs.

5.5. List any tests/procedures/interventions that will be required due to the introduction of the test. If this test is required to stratify a drug treatment, please state.

5.6. If the test is currently provided from laboratories elsewhere in the UK, please state the name of the laboratory and the cost of the test.

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Molecular Pathology Steering Group

NHS National Services Scotland

- Consideration given to all information provided:
- Common test appropriate for 4 centre delivery model or rare test – low volume best delivered in one centre
- Cost of testing
- Local availability of clinical expertise
- How does the test fit in with other pathways
- Practicalities of transporting specimens from one site to another – clinical risks

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Challenges and opportunities

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Challenges

- Balancing increased demand for testing and maximising clinical utility within resource limitations
- Technological advancement
- Sample size and requirements for testing
- NHS IT infrastructure
- Delivery of staff training and supporting CPD

Opportunities

- Think global, act local - embedding molecular testing within the patient pathway is best achieved through a Consortium working at both local and national levels
- Avoidance of a postcode lottery
- Effective business continuity planning
- Effective communication and strategic planning will enable different developments to take place on four sites
- The development of local scientific and clinical areas of expertise contributes to a greater combined scope for the Consortium

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Thank you

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