Joint Working Agreement - Executive Summary

1. Project Name:	RET (Rearranged During Transfection) Gene Validation. Start Date: 1st March 2022
2. Organisation involved with the JWA:	Liverpool University Hospitals NHS Foundation Trust, pathology service.
3. The objectives for this project are:	▪ To validate RET gene on the laboratory's operating system, Biocartis, Idylla Platform and alternative technologies ▪ To provide an essential salvage pathway enabling equitable access to diagnostics for all patients with NSCLC (Non-Small Cell Lung Cancer) referred to Pathology services at The Liverpool University Hospital during transition to a fully operating GLH. ▪ To provide an alternate testing route when there is; Insufficient tissue biopsy material, Low neoplastic content (10-20%) or Clinical urgency.
4. Roles and Responsibilities, including any funding	**Lilly UK:** ▪ Sourcing *RET* +fusion tissue samples from either UK pathology sites, biobanks or commercial companies: Clinical Diagnostic Scientist (CDS). ▪ Arranging any Infrastructure needs to ship or transport the tissue samples to the local laboratory: Lilly Procurement and CDS. ▪ Support any project documentation or final reports. (Lilly will not have any insight into patient identifiable data during this project or handle the tissue samples). (Lilly's National Access Manager (NAM) and CDS) **Liverpool University Hospitals NHS Foundation Trust pathology service:** ▪ The Liverpool University Hospital pathology services to continue sourcing *RET+* NSCLC tissue samples until validation of the Idylla Platform and alternative testing platforms is complete. ▪ Post validation of the Idylla Platform to communicate a testing algorithm and pathway to signpost referring laboratories to either the GLH or The Liverpool University Hospital Pathology Services. **Financial Arrangements of Lilly UK:** ▪ Cost of tissue biobank administration fee (The Christie) £100 ▪ Supply of tissue sections £50/year (The Christie) ▪ Validation and transfer of tissue to Liverpool University Hospital Pathology Service (GenQA) £2,166.50 / sample, Total Cost £6,499.50 ▪ Lab costs for cartridge £150 each x6 = £900 ▪ Miscellaneous laboratory consumables = £170 ▪ Clinical Diagnostic Scientist (Agenda for change scale 8c) £56,665 to £73,664[1] (10 days) daily rate £283 = £2,830 ▪ Project support, Band 8a £51,668[1] (3 days) daily rate £198.72 = £596.61

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	Financial Arrangements of Liverpool University Hospital NHS Foundation Trust pathology service: Clinical laboratory time and administration of validation and subsequent pathways. ▪ Consultant pathologist (5 days) £87,238[1] PA/260 days daily rate £336.53 daily rate x 5 = £1,677.65 ▪ Biomedical scientist Band 6 (5 days) £42,311[1] PA/260 days daily rate £149.34 x 5 = £746.70
The expected benefits for patients on delivery of this project are:	▪ Validation of assays to detect actionable markers like RET, will Increase the number of people accessing early and accurate diagnosis enabling patients to receive targeted more effective therapies with less adverse events. ▪ In clinical trial patients who had previously received at least platinum-based chemotherapy, the percentage with an objective response to the active biomarker for RET+ fusions were 64%[2] ▪ Patients had an average of 16.5 months progression free survival in the clinical trial with a RET inhibitor medication.[2]
6. The expected benefits for the partner organisation(s) on delivery of this project are:	▪ Extended access to molecular diagnostics for NSCLC, offering multi-gene RT-PCR testing routinely to all people with NSCLC. ▪ Matching people to the most effective medications and interventions, reducing the likelihood of an adverse drug reaction extension of progression free survival rates of 16.5 months.[2]
7. The expected benefits for Lilly UK on delivery of this are:	▪ By supporting the validation of the Idylla Platform, RET fusion testing will be accessible during the transition to the GLH in The Liverpool University Hospital pathology catchment. This may increase access to a Lilly medication.

References

1.https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1005011/NHSPRB_2021__Report_-_Web_accessible_version.pdf

2. New England Journal of Medicine, Efficacy of Selpercatinib in RET Fusion–Positive Non–Small-Cell Lung Cancer, August 27, 2020, vol. 383 no. 9