Collaborative Working Agreement Summary

1. Project Name:	Lilly and Betsi Cadwaladr University Health Board Collaborative Working Agreement - Breast Cancer Optimal Cancer Pathway Analysis
2. Organisations involved with this Collaborative Working Project are:	Eli Lilly and Company Ltd and Betsi Cadwaladr University Health Board (BCUHB)
3. The objectives for this project are:	The purpose of this project is to support the breast cancer pathway review. To assess the current demand on the National Optimal Pathway from the six entry points to patients exit from the service. (e.g. Day 10, 21, 28 etc.) Although it is known that there are delays in the pathway the project will aim to identify pinch points at critical time points, notable in radiology and outpatients. The project will analyse processes where required, providing insights on the breast cancer diagnosis pathway using local anonymised and aggregated data owned by BCUHB. Patient confidentiality will be always maintained. Data-informed insights will aim to address key critical areas for change, bottlenecks, resourcing issues, scanner, machine capacities and constraints and what might be contributing to diagnostic target breaches. The project will assess current capacity in early and metastatic pathways and provide insights on additional workforce requirements to meet the demand on SACT delivery in 2024 and potential changes to treatment pathways in the following year. The methodology and data used to baseline capacity for radiology requirements can be inserted into an optimization tool provided by National Physical Laboratories (NPL) for radiology requirements to assess peaks and troughs in demand. On completion of the project, use of the optimization tool will be considered to assess potential trends in demand and how to plan for peaks in demand to support attainment of targets. The optimization tool is not included in the project. The project outcome data sets will be evaluated both during and upon completion of the project. Evaluation of insights gained will be incorporated into an internal BCUHB review to identify areas for improvement. This evaluation will mark the conclusion of Lilly's involvement.
4. Roles and Responsibilities, including any funding	**Lilly UK:** ● Joint development of all documentation required for a Collaborative Working Agreement (CWA), under Clause 20 of the ABPI Code of Practice 2021 – Collaborative Working. Review and consider code changes pending in 2024/2025. ● Project Management support as required such as minute taking and dissemination, maintaining project logs, stakeholder engagement activities. ● Responsible for the organising of regular project group meeting and gate / stage reviews. ● Part funding of the project to allow additional data analysis from National Physical Laboratory to ensure all pathway mapping is completed in areas outside of the responsibility of Lilly. Data analysis will be only in those areas within scope of the CWA.

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	● Mapping of 6 clinical pathways to determine patient flow and provide NPL with data for radiotherapy evaluation. ● Data analysis at each critical time point using localised data where available to assess patient numbers and pinch points of demand. ● Evaluation of processes and procedures from the six entries of the Single Cancer Pathway to patient exit from the service. ● Final report with insights from Lilly and National Physical Laboratory. ● Review of materials developed under the course of the project and certification as required in line with the ABPI code of practice. ● Facilitation of any workshops required to implement the project namely stakeholder engagement meetings. ● The CWA executive summary will be publicly available on the Lilly UK corporate website and in the ABPI repository before the project is initiated. ● Joint dissemination and ownership of results (final report) including publication in relevant trade and / or clinical press within 6 months of project completion. ● Lilly to support in creating poster / presentation / publication of any benefits realised because of this collaborative working process and certification of this material. ● Joint commitment with Betsi Cadwaladr University Health Board to demonstrate any benefits realised during this project to the NHS on a wider scale. ● In the unlikely event any Lilly employee is made aware of an adverse event it is their responsibility to report this as per the Lilly local process. ● Any decision made under the course of this project should be in line with existing local and / or national clinical guidelines. Lilly will have no influence over any prescribing or clinical decisions. ● Lilly will not have access to any patient identifiable information at any point in the project. ● Disclosure of value is published annually on the 'Disclosure UK website'. **Partner Organisation:** ● Joint development of project initiation documentation. ● Understanding and navigation of Trust process for entering into a Collaborative Working Agreement with Lilly UK. ● Provision of suitably qualified project lead to oversee project delivery. ● Stakeholder engagement at a strategic NHS level. ● Providing relevant healthcare professionals, management personnel, and administrative staff to collaborate with Lilly and National Physical Laboratories for data analysis and the identification of necessary processes and procedures. ● Anonymised data extraction of clinical data where specified for the project in section 3 and appendices 1 and 2. ● Ensuring an ethically approved method for collecting patient diaries detailing their breast cancer journey, while safeguarding consent and maintaining anonymity. No patient reported outcome data will be collected; only aggregated data will be processed as part of the CWA; at no point will Lilly have

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	access to patient-identifiable data. Joint (with Lilly UK) funding for additional clinical and managerial time required to implement the project. ● Joint (with Lilly UK) funding for NPL time required to implement the project. ● Data privacy agreements to be arranged with other providers (NPL) for data extraction and schedule of work. ● Adverse event reporting using standard reporting process. ● Provide Lilly with any materials developed within the scope of this project for Lilly to review and, if necessary, approve before use. Lilly may require amends to these materials to ensure compliance with the ABPI Code of Practice. ● In addition to the Project Initiation Document, the ABPI Code of Practice 2021 requires other material relating to collaborative working to be certified, including the executive summary of the agreement. ● Responsibility for the core stakeholders to review recommendations made in the final report. ● Evaluation of project outcome data sets documented in section 3 of this PID, during and on completion of the project to build into an internal review to evaluate areas where insights could be considered to improve eligible patients starting breast cancer treatment within 62 days in reference to the internal target of 65%. This will conclude Lilly's involvement. ● Stakeholder engagement at a strategic NHS level to ensure value of the project and possible replication of methodology to other health boards in Wales if a proof of concept is achieved. Replication of this project is outside the scope of this CWA. ● Jointly (with Lilly UK) publish results of the project within 6 months of completion of project, in relevant clinical and trade press or at National meeting/conference. Such publication may be subject to approval under the ABPI code, and Lilly may require amends to this effect. **Funding arrangements:** **Estimated project costs** Lilly cash contribution £55,279.87 Lilly staff resource dedicated to the project £21,727.82 Betsi Cadwaladr University Health Board staff resource costs estimated £47,433.12
5. The expected benefits for the partner organisation(s) on delivery of this project are:	● Resource needs will be based on local data to support clinical leads and service managers to submit robust business cases for additional capacity to meet operational targets. ● Insights in the final report will provide an option appraisal to identify potential solutions which require low resource but high impact due to financial constraints in the health board. ● The project may identify system changes to improve efficiency without financial implication to the health board. ● A framework to plan a more efficient service delivery plan in the long term.

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6. The expected benefits for Lilly UK on delivery of this are:	Insights provided during the analysis of the optimal breast cancer pathway if implemented could result in a greater number of patients accessing appropriate treatment, some of whom may be prescribed a Lilly manufactured medication. Any decision made under the course of this project should be in line with existing local and / or national clinical guidelines. Lilly will have no influence over any prescribing or clinical decisions. Publication of this project would demonstrate Lilly to be a valued partner to the NHS in innovation and may strengthen the Lilly Oncology brand reputation.