Joint Working Agreement Summary

1. Project Name:	Phased programme for ultrasound technology utilisation in gastroenterology departments in the UK
2. Organisations involved with this Joint Working Project are:	Eli Lilly and Company Ltd and Barts Health NHS Trust
3. The objectives for this project are:	The project will aim to establish a sustainable phased programme for gastroenterology departments in the UK to complete module 2 of the International Bowel Ultrasound group (IBUS) curriculum for standardised high-quality techniques for an Intestinal Ultrasound (IUS) examination. This is for the purpose of diagnosing and monitoring Inflammatory Bowel Disease (IBD). The current process for diagnosing IBD in the UK includes a colonoscopy and this project aims to support a change in service delivery from colonoscopy in the UK to IUS, as seen in other European countries. The project will plan and cost the benefit of a UK programme where there are regional certified IBUS centres to provide sustainable and accessible locations to all gastroenterology departments in the UK. Criteria for certification of a site is set by IBUS. Phase 1. Modules 1 to 3 of the IBUS group curriculum as follows: • Set up an accessible module 2 programme for an initial group of UK gastroenterologists or radiologists who have completed module 1 to ensure that the course can be completed within a maximum of one year. This Includes four-weeks of practice skills in bowel ultrasound, to be performed in a certified IBUS centre (Barts NHS Trust, following IBUS certification of sufficient clinical staff members). • Record the number of clinicians who have completed modules 1 to 3 by NHS site during the timeframe of the project who intend to provide module 2 in the future. (NHS trust must have sufficient patient volume to sustain module 2 requirements as per IBUS requirements). Phase 2. Develop a map of regional centres across the UK to ensure sustainability for future module 2 requirements. • Map the expected number of UK gastroenterologists and or radiologists who will want to utilise IUS in their clinics over the next 5 years. • Map the number of regional centres required to meet the estimated demand of UK clinicians requiring IUS over the next 5 years. The regional centres should have the volume of patients required to sustain the IBUS requirements for number of scans required per clinician to meet the competence of the IUS procedure. • Support applicants from Phase 1 to plan for service change with a business case or top tips guide (if required) to start the early expansion of module 2 locations. • Track any barriers in these planned centres to ensure they meet the requirements for a certified IBUS centre (protocols, governance, resource, and costs etc).

Joint Working Agreement Summary

	• Support to generate a business case for ultrasound equipment required for gastroenterology departments to consider a change of practice from colonoscopy to IUS in IBD. • Support a service transformation guide for other Trusts to follow. • Track a robust Return on Investment (ROI) to sustain module 2 costs in the long term with a national organisation.
4. Roles and Responsibilities, including any funding	**Lilly UK:** ● Joint development of all documentation required for a Joint Working Agreement (JWA), under Clause 20 of the ABPI Code of Practice 2024 –Joint Working. ● Project lead with additional 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. ● Facilitation of any workshops required to implement the project namely stakeholder engagement meetings. ● Part funding of the project to build the resource capacity required for module 2 in the UK. Lilly will not be involved in the selection of delegates to attend module 2 at Barts Health NHS trust. Lilly will not be involved in creation of the IUS training agenda or content. ● Support to generate a business case for ultrasound equipment required for gastroenterology departments to consider a change of practice from colonoscopy to IUS in IBD. ● Development of a top tips guide to support NHS Trusts to implement the service change required to implement IUS for IBD. ● In addition to the Project Initiation Document, the ABPI Code of Practice 2024 requires review of all final materials developed under the course of the project to be certified, including this executive summary of the agreement which will be publicly available on the Lilly UK corporate website and in the ABPI repository before the project is implemented. ● National mapping of gastroenterology and radiology consultant posts to establish an estimated demand for IUS learning over a 5-year period. ● National mapping of regional centres required to meet the IUS learning demand over a 5-year period. ● Initial tracking of ROI in new NHS services adopting IUS with continued tracking by NHS when Lilly's involvement has concluded. ● Certified final report with recommendations for a sustainable module 2 programme in the UK for the IBUS curriculum over the next 5 years. This will include a ROI which can be used with relevant national organisations such as the British Society of Gastroenterology to secure module 2 budget when Lilly withdraws from the project. Completion of the report will conclude Lilly's involvement. ● Joint dissemination of the results in a certified final report including publication in relevant trade and / or clinical press within 6 months of project

Joint Working Agreement Summary

	completion. Such publication may be subject to approval under the ABPI code, and Lilly may require amends to this effect. ● Lilly to support in creating poster / presentation / publication of any benefits realised because of this joint working process and certification of this material. ● Joint commitment with Barts Health to demonstrate any benefits realised during this project to the NHS on a wider scale. ● Any clinical and/or prescribing 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 a Joint Working Agreement with Lilly UK. ● Provision of suitably qualified project lead to oversee project delivery. ● Stakeholder engagement at a strategic NHS level for quality indicators and project sustainability to include: ○ A standardised approach to quality criteria for IUS competence including gastroenterologists, radiologists and nurse specialists. ○ Sustainable, ongoing module 2 costs. ● Provision of relevant health care professionals, management personnel and administration staff to work with Lilly for mapping or data analysis and where identified process and procedures for the development of a top tips guide for service change. ● Compliant collection of patients' questionnaires seeking feedback on the patients' experience of IUS compared to the previous colonoscopy intervention, safeguarding patient consent and maintaining anonymity. Patient reported outcome data; only aggregated data will be processed as part of the JWA; at no point will Lilly have access to patient-identifiable data. The patient questionnaire requires approval by Lilly prior to use which requires 4 weeks lead time, ensure this lead time is factored into the project plan. ● Joint (with Lilly UK) funding for resource required to implement the project. ● Full responsibility for selection of UK delegates registered for module 2 at Barts Health (delegates will need to have completed module 1 which is out of scope of this project). Delegates costs to travel, accommodation, subsistence, etc. related to module 2 is the responsibility of the delegates, this should be communicated by Barts Health NHS Trust IBUS co-ordinator. ● Full responsibility for creation of the IUS training agenda and content for module 2. ● Full responsibility for competence of delegates completing module 2 at Barts in liaison with IBUS. ● Adverse event reporting using standard reporting process.

Joint Working Agreement Summary

	● Provide Lilly with all materials developed within the scope of this project for Lilly to review before use. Lilly may require amends to these materials to ensure compliance with the ABPI Code of Practice. ● Responsibility for the core stakeholders to review recommendations made in the final report. ● Evaluation of project outcomes, during and on completion of the project to build into an internal review to evaluate a sustainable module 2 budget which will be shared with national organisations such as the British society of Gastroenterology. This will conclude Lilly's involvement. ● Stakeholder engagement at a strategic NHS level to ensure value of the project and continued support of the model. ● Jointly (with Lilly UK) publish final, approved 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. ● Full responsibility for clinical decisions made under the course of this project which should be in line with existing local and / or national guidelines. **Funding arrangements:** **Total cost of Project £110,996.31** Staff time (Lilly) £10,816.74 Financial contribution from Lilly towards full project minus Lilly time **£50,089.79** to be paid at the start of the Joint Working Agreement (JWA) December 2024. **Non funding arrangements:** Staff resources at Barts NHS Trust required for this project are estimated at £50,089.79
5. The expected benefits for the Patient	• Non-invasive tools for diagnostic and monitoring of the bowel replaces the need to adopt a 4-day preparation for colonoscopy for new and follow up appointments. • Patient satisfaction, shorter appointments with faster management decisions with the aim of improving quality of life. Patient reported outcome data; only aggregated data will be processed as part of the JWA; at no point will Lilly have access to patient-identifiable data. • Treatment (where appropriate) in line with the NHS constitution values and National Institute for Health and Care Excellence (NICE) guidelines.
6. The expected benefits for the partner organisation(s) on delivery of this project are:	• Rapid availability for point of use management decisions (including treatment) in outpatient appointments. • Low costs compared to usual care, endoscopy, and Magnetic Resonance Imaging (MRI). • Resource and time efficient for clinical teams. • Equity of care in line with international standards in Europe and Australia.

Joint Working Agreement Summary

7. The expected benefits for Lilly UK on delivery of this are:	A sustainable model for changing practice to ultrasound imaging, if implemented, could improve the efficiency of patient's pathways, with faster access to diagnosis, monitoring and appropriate management, which may include a Lilly manufactured medication in line with National Institute for Health and Care Excellence (NICE) guidance. Publication of this project would demonstrate Lilly to be a valued partner to the NHS in innovation and may strengthen the Lilly immunology brand reputation. Any clinical 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.