Joint Working Agreement Summary

1. Project Name:	**Risk Stratification and Optimisation for Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD)**
2. Organisations involved with this Joint Working Project are:	Eli Lilly & Company (Lilly UK) Sutton Primary Care Networks
3. The objectives for this project are:	This project aims to develop a new model of care for adult patients at risk of Metabolic Dysfunction-Associated Steatotic Liver Disease (MASLD) working with GPs from four practices. A protocol will be developed to include medications for the management and/or treatment of the patient's comorbidities as well as lifestyle interventions which are believed to improve outcomes for adult patients with MASLD, which supports the PCNs vision to improve patient outcomes. The project will seek to co-produce solutions with patient acceptability as key, which is crucial for addressing MASLD effectively. By acting on patient feedback from adult patients who live with MASLD, the project team will better understand the obstacles and barriers patients face in adhering to diet and lifestyle modifications. Gathering their views and suggestions on overcoming these obstacles will ensure that the new model of care developed remains patient centred. Lilly will not have any direct patient contact, and feedback will be sought via interviews with HCPs or pre-approved survey. This project's main objective is to develop and implement a comprehensive risk stratification protocol for adult patients at risk of MASLD, along with tailored medical and lifestyle optimisation strategies. This includes identifying high-risk and medium risk individuals, providing pharmacological management for their comorbidities (as appropriate) and encouraging lifestyle modifications to reduce liver fat and associated metabolic risks. The project will also aim to monitor and evaluate outcomes to assess the effectiveness of implemented interventions. The secondary aim of this project will be to test the Pro-Active Register Management (PARM) tool for Obesity. The project will evaluate the functionality of the prototype of the tool and other parameters. PARM-Obesity is a non-promotional tool Lilly is building to support primary care providers to better understand their patients with obesity and support the identification of patient cohorts for care optimisation. It is expected that the tool will be important to implementing locally designed pathways for people living with obesity, as well as assessing their impact. Primary care teams will have the ability to evaluate the impact of interventions by seeing the "before and after intervention" view of their cohorts. The intention is that PARM-Obesity will support Healthcare Professionals (HCPs) in identifying a category of high-risk and medium risk adult patients for MASLD, but it is not designed to be a clinical decision-making tool and is not linked to any treatments of comorbidities linked to MASLD.

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4.1 Roles and Responsibilities of Lilly UK.	• Joint development of all documentation required for a Joint Working Agreement (JWA), under Clause 20 of the ABPI Code of Practice 2024 Collaborative Working. • 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. • Review of materials developed during the project and certification as required in line with the ABPI code of practice. • Facilitation of any workshops as required to implement the project namely stakeholder engagement meetings. • Lilly to support in creating poster / presentation / publication of any benefits realised because of this Joint working process and certification of this material. • Joint dissemination and ownership of results (final report) including publication in relevant trade and / or clinical press within 6 months of project completion and certification of material. • Creation of patient pathway with escalation and referrals as required. • Joint commitment to demonstrate any benefits realised during this project to the NHS on a wider scale. • Any clinical and prescribing decisions made during 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. • The PARM Obesity tool is a prototype, the validated questions asked in this project will evaluate the functionality of the tool. The responses will be used by the Lilly PARM development team to build the final version of the tool which will be certified. During this test phase PARM does not extract any data from the practices. Data analysis occurs automatically within the Excel-based tool, without any data transfer or processing by Lilly or any third party. • Lilly to part fund the project. • Disclosure of value is published annually on the 'Disclosure UK website'. • Analyse Data provided by Sutton PCN as required. • Co-Development of Healthcare professionals (HCP) and patient questionnaires and patient interview questions. • Co-development of a scale plan for wider adoption of the model both within the ICB and the wider NHS as appropriate. • Provision of PARM Obesity Tool prototype and training. • In addition to the Project Initiation Document, the ABPI Code of Practice 2024 requires that Lilly reviews all material prior to use and any final materials relating to joint working need to be certified, including the executive summary of the agreement.

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4.2 Roles and Responsibilities of Partner Organisation(s)	• Understand and manage Central Sutton governance process for entering into Joint Working Agreements with the pharmaceutical industry. • Co-product the Project Initiation Document in line with project deliverable and outcomes. • Stakeholder engagement and management across PCN as required. • Co-fund the project. • Validate the use of PARM Obesity tool and provide feedback to Lilly. • Deliver relevant intervention as per project outline and objectives. • Provide anonymised data to Lilly for analysis. • Responsibility for any data sharing agreement between Lilly and Sutton PCN. • Co-develop any poster / presentation / publication of any benefits realised because of this joint working project which will be certified by Lilly. • Co-development of a scale plan for wider adoption of the model both within the ICB and the wider NHS. • Hiring of any equipment required for this project is the responsibility of the PCN/ GP Practice, and they must make sure that all quality assurance procedures are met throughout the duration of the project. • Co-development of Health Care Professional (HCP) and patient experience questionnaires. • Ensure that if any licences are required to utilise validated tools as part of this project are procured by the GP/PCN and maintained for the duration of the project. • Any Apps or tech used for this project is the full responsibility of the PCN. • All materials must be provided to Lilly for approval before use. • Central Sutton PCN is responsible for any for any treatment or clinical decisions made under the course of this project. Any prescribing should be in-line with existing local/national clinical guidelines.
5. The expected benefits for patients on delivery of this project are:	By having a holistic approach to the management of adult MASLD patients and those at high risk of developing MASLD, it is anticipated that there will be improvements in the following clinical outcomes: % improvement of HbA1c (pre diabetics and established Type 2 Diabetes Mellitus (T2DM) % reduction in Body Mass Index (BMI) % reduction in Blood pressure (BP) % reduction in Cholesterol Improvement of Liver function test (LFT) As well as patient adherence, this project will be addressing important unmet needs in diverse and socioeconomically disadvantaged communities.
6. The expected benefits for the partner organisation(s) on delivery of this project are:	The findings and model established through this project will lay a strong foundation for future initiatives within the healthcare setting and improving patients' outcomes across the PCN/ICB. These will be aimed at addressing metabolic disorders associated with the development of MASLD and improving patients' outcomes across the PCN/ICB.

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	This project will also aim to reduce the pressures on secondary care referrals by carrying out diagnostic testing within the primary care setting. This project will aim to develop a centre of excellence within the PCN which will help reduce the need for patients to be referred to secondary care services.
7. The expected benefits for Lilly UK on delivery of this are:	• Should Lilly decide to replicate this project in other NHS organisations, subject to separate approval, it will further reinforce Lilly's reputation to be a valued partner to the NHS in innovation and may strengthen the Lilly brand reputation. Publication of this project will further demonstrate Lilly to be a partner in innovation with the NHS. • This project will give valuable insights into different models of community care for MASLD patients that Lilly may use as the basis of further Joint Working projects, or Donations of service aimed at optimising obesity care. • Lilly will have no influence over any clinical and/or prescribing decisions made during this project and any prescribing of medicines is expected to be in line with existing local or national guidelines. As a pharmaceutical manufacturer of medicines for some comorbidities linked to MASLD, an indirect result of optimising care pathways may be that Lilly sees a potential result in the prescribing of Lilly medicines for eligible patients where clinically appropriate.