

## Executive Summary

### A Collaborative Working Project between Bristol-Myers Squibb Pharmaceutical Limited (“BMS”) and Barts Health NHS Trust (“Barts”)

<b>Project title</b>	Implementation of ESC Guidelines for the Management of Cardiomyopathies through the Sustainable Expansion of a Nurse-Led LVOT Obstruction Clinic in Collaboration with Barts Health NHS Trust
<b>Project rationale</b>	Hypertrophic cardiomyopathy (HCM) is a common inherited heart condition, with approximately one-third of patients experiencing significant symptoms due to left ventricular outflow tract (LVOT) obstruction. Traditional management has relied heavily on invasive procedures, but recent advances, particularly myosin inhibitors, as recommended in the 2023 European Society of Cardiology (ESC) Guidelines, offer promising non-invasive alternatives. The Barts Heart Centre ICVD service, the UK's leading provider of HCM care, established the nurse-led, consultant-supervised Novel OutFlow Tract Obstruction (NOLTO) clinic in May 2024 to address the needs of these patients. Demand for care and growing referral numbers have led to capacity challenges and extended waiting times, necessitating an expansion of the clinic.
<b>Project objectives</b>	<p>This collaborative project between Barts Health NHS Trust and Bristol Myers Squibb (BMS) aims to optimise care for individuals with HCM and LVOT obstruction by sustainably expanding the NOLTO clinic and integrating the ESC 2023 Guidelines into clinical practice. The overarching goal is to improve patient access to evidence-based, high-quality care, reduce waiting times, and further enhance clinical outcomes for patients with obstructive HCM.</p> <ul style="list-style-type: none"><li><b>Objective 1:</b> Integrate the ESC 2023 Guidelines for the management of cardiomyopathies into the NOLTO clinic's operations, ensuring alignment with best practice and international standards.</li><li><b>Objective 2:</b> Expand the nurse-led, consultant-supervised NOLTO clinic from one to two days per week over a 24-month period, improving access and service capacity.</li><li><b>Objective 3:</b> Develop a ‘best practice’ model based on lessons learned, to inform future ICC/HCM-focused clinics across the UK.</li></ul>

	<p><b>Expected benefits</b></p> <p>For patients:</p> <ul style="list-style-type: none"> <li>• A greater number of patients receive evidence-based and guideline-driven care, improving their experience within the healthcare system.</li> <li>• Improved patient outcomes through reduced waiting times and access to specialised care.</li> </ul> <p>For Barts:</p> <ul style="list-style-type: none"> <li>• Service enhancements that can serve as a best practice model for other centres looking to implement an ICC or HCM-focused clinic.</li> <li>• Increased efficiencies in patient management through multidisciplinary team (MDT) integration and guideline-based pathway redesign.</li> <li>• Improved healthcare outcomes for the local community.</li> </ul> <p>For BMS:</p> <ul style="list-style-type: none"> <li>• Reputational benefits from collaboration with a leading ICC centre.</li> <li>• The opportunity to develop and showcase a best practice model that can be shared across the NHS, facilitating potential implementations in other regions.</li> <li>• Contribution to the HCM and ICC space, improving patient outcomes by enhancing access to care.</li> </ul>
<b>Project period</b>	<p>The project will be delivered in four phases:</p> <ol style="list-style-type: none"> <li>1. <b>Setup:</b> Establish an additional nurse-led clinic day and complete staff training (Months 1-3). Expected to start in Q4 2025.</li> <li>2. <b>Implementation:</b> Operate the expanded clinic, duplicating successful current practices and increasing staffing (Months 3-27). Expected to start in H1 2026.</li> <li>3. <b>Assessment &amp; Optimisation:</b> Review workflows and gather feedback to minimise wait times and improve patient experience (Months 15-27). Expected to start in H1 2027.</li> <li>4. <b>Data Analysis &amp; Dissemination:</b> Analyse clinic data and prepare findings for peer-reviewed publication and presentation (Months 27-30). The project is expected to come to an end in H1 2028.</li> </ol>
<b>Financial arrangements</b>	<p>The project will be jointly funded, with Barts and BMS each contributing approximately 50% of the total annual budget. The total maximum contribution expected from Barts is £597,244.46 (298,622.23 per year) and from BMS is £600,446 (£300,223.00 per year), outlined in detail in the Project Initiation Document.</p>

<b>Plans for publications</b>	<p>The development and publication of key learnings, including best practices, effective and ineffective implementation strategies, barriers, facilitators, and practical examples are in scope for this collaboration. All outputs, including the development and publication of key learnings, including best practices, effective and ineffective implementation strategies, barriers, facilitators, and practical examples are in scope for this collaboration, in the form of manuscripts, congress posters, or presentations, will be led by Barts and agreed in conjunction with BMS. Efforts will be made to submit findings to high-impact journals or present at professional conferences within six months of project completion, with all publications and materials developed and ratified by the project board prior to dissemination.</p> <p>The project will adhere strictly to the ABPI Code of Practice, NHS policies, and relevant guidelines. All communications, publications, and outputs will undergo appropriate review and certification. Robust safety reporting, pharmacovigilance training, and data privacy procedures will be enforced.</p>
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<b>Summary of the roles and responsibilities of each party</b>	<p>The Healthcare Organisation:</p> <ul style="list-style-type: none"><li>• NOLTO Clinic expansion setup and execution, ensuring compliance with applicable laws along with NHS policies and practices</li><li>• Recruitment, engagement, employment, training (save in respect to BMS product safety reporting) and supervision of non-BMS personnel involved in the Project</li><li>• Data audit and presentation</li><li>• Act as data controller</li><li>• Development of report with key learnings</li><li>• Development and write up of publication/s for peer-reviewed journal/congresses</li><li>• Co-development of publication plan</li></ul> <p>BMS:</p> <ul style="list-style-type: none"><li>• Training of stakeholders on AEs &amp; safety reporting</li><li>• Lead and organise regular touchpoints related to Project objectives</li><li>• Co-development of publication plan</li></ul>

Role/Activity	Barts	BMS
Training of stakeholders on AEs & safety reporting		X
NOLTO Clinic expansion setup and execution, ensuring compliance with applicable laws along with NHS policies and practices	X	
Recruitment, engagement, employment, training (save in respect of BMS product safety reporting) and supervision of non-BMS personnel involved in the project	X	
Data audit and presentation	X	
Act as data controller	X	
Lead and organise regular touchpoints related to project objectives		X
Development report with key learnings	X	X
Development and writing publication for peer-reviewed journal/congress poster	X	

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