

Sponsorship Proposal Over £5k

Governing Body meeting

6 August 2020

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Author(s)	Mr Gary Barnfield, Head of Medicines Management
Sponsor Director	Alun Windle, Acting Chief Nurse
Purpose of Paper	
<p>The Standards of Business Conduct and Conflicts of Interest Policy and Procedure requires that all proposals for sponsorship over £5k are approved by Governing Body. This paper is seeking approval for the proposal outlined in the attached appendices.</p>	
Key Issues	
<p>Astra Zeneca has offered sponsorship to Sheffield CCG in order to support a project which aims to improve long term outcomes for ethnic minority patients with diabetes. The specific aims of the project are to engage with patients with complex needs, complex risk factors. This is in line with the strategic aim of the CCG to reduce variation of care and increase access for hard to reach patient groups.</p> <p>The value of the sponsorship is £15k which will be paid direct to a support Pharmacist who can speak Urdu thus allowing cultural and linguistic barriers to be overcome.</p> <p>The Gifts, Hospitality and Sponsorship Form is included at Appendix 1, together with the actual sponsorship proposal which is included at Appendix 2.</p>	
Is your report for Approval / Consideration / Noting	
Approval	
Recommendations / Action Required by Governing Body	
<p>The Governing Body is asked to approve the attached proposal for sponsorship to the value of £15k from Astra Zeneca to support a project which aims to improve long term outcomes for ethnic minority patients with diabetes.</p>	
What assurance does this report provide to the Governing Body in relation to Governing Body Assurance Framework (GBAF) objectives?	
<p>Which of the CCG's Objectives does this paper support?</p> <p>1. Reduce the impact of health inequalities on peoples' health and wellbeing through working with Sheffield City Council and partners</p>	

Are there any Resource Implications (including Financial, Staffing etc)?
This investment in the project will be matched by the CCG in provision of practice based pharmacists for the project and protected mentoring access to HCPs who provided the existing Diabetes Service.
Have you carried out an Equality Impact Assessment and is it attached?
Please attach if completed. Please explain if not, why not No specific issues associated with this report
<i>Have you involved patients, carers and the public in the preparation of the report?</i>
N/A

GIFTS, HOSPITALITY AND SPONSORSHIP FORM

This form must be completed **in advance** of Sponsorship being accepted, and, wherever possible **in advance** of any acceptance of gifts (with a value in excess of £10) or hospitality.

1. Declaree	
Name of recipient:	Gary Barnfield
Role:	Deputy Director Medicines Optimisation (AHPs)
2. Details of gift / hospitality / sponsorship (please tick relevant box and complete following sections in full)	
<input type="checkbox"/> Gift	<input type="checkbox"/> Hospitality <input checked="" type="checkbox"/> Sponsorship
Date of offer:	25/06/2020
Details of offer: <i>(please include the reason for the offer, if known)</i>	<p>Astra Zeneca has offered sponsorship to Sheffield CCG in order to support a project which aims to improve long term outcomes for ethnic minority patients with diabetes.</p> <p>The Specific aims of the project are to engage with patients with complex needs, complex risk factors. This is in line with the strategic aim of the CCG to reduce variation of care and increase access for hard to reach patient groups.</p>
Estimated value:	£15,000
Supplier / Offerer name, nature of business and address: <i>(If hospitality is received, please also provide name and address of hospitality venue)</i>	<p>ASTRAZENECA UK LIMITED</p> <p>1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA</p>
Details of previous offers or acceptances from this Supplier / Offerer:	None
3. Action taken (please tick relevant box and complete following sections in full)	
<input type="checkbox"/> Declined	<input type="checkbox"/> Accepted
Reason for accepting or declining:	

JOINT FRAMEWORK FOR BUSINESS CASE

NHS Sheffield CCG & ASTRAZENECA UK LIMITED, 1 Francis Crick Avenue, Cambridge Biomedical Campus, Cambridge CB2 0AA

Document Control

Version	Issue Date	Version	Issued To	For: decision / discussion / noting etc. (insert below as appropriate)
<i>1</i>	25/6/20	<i>X</i>	Gary Barnfield	Discussion
<i>2</i>	27/7/20	<i>Y</i>	Gary Barnfield	Discussion
<i>3 etc.</i>		<i>Z etc.</i>		

1. JOINT WORKING PROJECT SUMMARY	
1. Title of Project	Sheffield Diabetic Services Mentoring Project
2. Background	<p>Sheffield has a registered population of 613,000 which is cared for by 79 GP Practices and Northern General and Hallamshire hospitals. In 2017/18 there were 31,436 people, aged 17 years or older, who had been diagnosed with diabetes on GP Registers in Sheffield CCG. This equals 6.4% of the population. However, the total prevalence of people with diabetes, diagnosed and undiagnosed, is estimated to be 8.2% which equates to roughly another 10,000 patients. A person with diabetes has a higher risk of cardiovascular complications (heart attack, angina, heart failure and stroke) and microvascular (amputation and renal disease) complications. In this area, people with diabetes were 104.8% more likely than people without diabetes to have a heart attack. People with diabetes were also 59.9% more likely to have a stroke. Statically People with diabetes are more likely to die than their peers of the same age and sex in the general population. The additional risk of mortality for people with diabetes was 18.1% in NHS Sheffield CCG. In 2018/19the admission rate for CHD and Diabetes is significantly higher than the England rate.</p> <p>Due to Covid 19 Diagnoses, investigations, treatment initiation and reviews are all down, the result is now more than ever we have a requirement to support Diabetic Clinic's response to patients' needs.</p> <p>The Practice Pharmacist team while all highly skilled have mixed experience in running Diabetics Services.</p>
3. Summary of Intended Aims and Objectives	<p>The objective of this project is to improve long term outcomes for patients with diabetes.</p> <p>The Specific aims of the project is to engage with patients with</p>

complex needs, complex risk factors and ethnic minorities. This is in line with the strategic aim of the CCG to reduce variation of care and increase access for hard to reach patient groups.

An assessment will be made of the patients' needs, an appropriate test carried out/ requested. Medicines optimised and appropriate referral to a specialist or wider health and social care team.

Finally, a follow-up care plan will be put in place, including a holistic patient assessment, diet/lifestyle advice and stress management. Food diaries and culturally sensitive diet leaflets will be provided.

All patient interactions would be recorded in the patient record ensuring there is clinical governance. The aim is to allow complex High-risk patients to have quicker access to an intensive specialist. This project is designed to offer additional support for Practices who have a South Asian Population. Our support Pharmacist can speak Urdu thus allowing cultural and linguistic barriers to be overcome. By ensuring a culturally sensitive service takes place there will be better patient engagement and they will have the tools to manage their condition better and be empowered to take control of their diabetes. This will lead to improved diabetes outcomes as Alia previously demonstrated by the "MELT" service (Minority Ethnic Long Term medicines Service) which operated for over a decade.

Format/milestones of the Project

The Format will be tailored to the practice needs in the form of Physical Clinics and mentoring.

The key milestones will be

- Practice engagement and tailoring project to meet Practice needs.
- First clinic
- 2nd Clinic
- Follow up clinic.
- Virtual mentoring for follow up clinics within the time frame of the project within the 4 months
- time frame of the project.

The following outcomes will be measured,

- Improvement in HbA1c,
- Weight,
- Blood pressure

	<ul style="list-style-type: none"> • Foot care • Dietary Advice • Follow up engagement by the Patient
<p>4. Summary of Expected Benefits</p>	<p><u>The benefit to patients.</u></p> <ul style="list-style-type: none"> • More geographically convenient appointments • Increased accessibility to diabetes review for those patients who may struggle to access the • surgery. • Targeted appointment times, which will allow for more individualised care • Better Control of their condition by treatment by treatment within Local Guidelines and National Guidelines and review by a Diabetes Specialist. • More appropriate treatment to prevent progression of the disease and Prevent Hospitalisations • Enhanced patient education. <p><u>Benefits to Practice.</u></p> <ul style="list-style-type: none"> • Improved Diabetes health outcomes for the locality. • Potential to reduce healthcare utilisation costs: <ul style="list-style-type: none"> o Fewer GP visits o Fewer hospital visits o Fewer A&E visits o Reduced long term healthcare costs associated with Diabetes <p><u>Benefits of PCN/ CCG</u></p> <ul style="list-style-type: none"> • Project is in line with strategic plans to reach difficult to reach patients and reduce variances across diabetic care <p><u>Benefits for Astra Zeneca.</u></p> <ul style="list-style-type: none"> • The project may identify patients who are suitable for one or more of our products, in line with national and local policies and guidelines • Improved relationship between the NHS and AstraZeneca in line with ABPI and NHS England Guidelines
<p>5. Summary of Expected Outcomes</p>	<p>The aim of this project is to enhance Diabetic Service in practice to help reach difficult to reach patients and reduce variances of care in line with the strategic plans of the locality.</p> <p>The expected outcomes of the project are:</p> <ul style="list-style-type: none"> • Delivery of target clinics to engage Patients of a south East Asian ethnicity to improve patient engagement with their treatment.

	<p>Referrals to specialist care</p> <p>Reduction of unnecessary appointments / admissions</p> <ul style="list-style-type: none"> • Support and mentoring for the Practice based pharmacist • One to one mentoring in all aspects of Diabetes Service provision. • Support and Mentoring for the Diabetes service in the Practice <p>Discussion re engagement with hard to reach patients</p> <p>Reduction in Variances</p> <p>Treatment of Patients to prevent unnecessary appointment and admissions.</p>
6. Start Date	Provisional start date of 1 st Sept. 2020
7. Finish Date	Each pilot will take 4 months and the whole project will be completed in 18 months provisional completion date Feb. 2022

2. PROJECT ORGANISATIONAL STRUCTURE	
1. Project Board / executive	<p>Gary Barnfield Deputy Director Medicines Optimisation (AHPs) Sheffield CCG</p> <p>Charlotte McMurray MOT Diabetes Lead Sheffield CCG</p> <p>Dr Jenny Stephenson Clinical Lead Sheffield CCG</p> <p>John Butler Astra Zeneca</p>
2. Project Manager	<p>Dr Jenny Stephenson Clinical Lead Sheffield CCG</p> <p>John Butler Astra Zeneca</p> <p>Representative from Pilot Practice</p> <p>Alia Giliane Pharmacist</p>
3. Joint Working Group	<p>Gary Barnfield Deputy Director Medicines Optimisation (AHPs) Sheffield CCG</p> <p>Charlotte McMurray MM Diabetes Lead Sheffield CCG</p> <p>Dr Jenny Stephenson Clinical Lead Sheffield CCG</p> <p>John Butler Astra Zeneca</p> <p>Representative from Pilot Practice</p> <p>Alia Giliane Pharmacist</p>
4. Stakeholders	<p>Gary Barnfield Deputy Director Medicines Optimisation (AHPs) Sheffield CCG</p> <p>Charlotte McMurray MM Diabetes Lead Sheffield CCG</p> <p>Dr Jenny Stephenson Clinical Lead Sheffield CCG</p> <p>John Butler Astra Zeneca</p> <p>Representative from Pilot Practice</p> <p>Alia Giliane Pharmacist</p>
5. Project Scope and Outline Plan	<p>Each Pilot will have the following</p> <p>Introduction meeting to practice</p> <p>(Identify patients to be reviewed)</p> <p>1st Clinic</p>

	<p>2nd Clinic 3rd Clinic Bespoke mentoring for PBP and HCPs in Service Review of project.</p>
6. List Those With Designated Responsibility for Each Stage of the Proposal	<p>Dr Jenny Stephenson will recruit a maximum of 6 pilot practice Alia Giliani will deliver introduction meeting and Clinics Alia Gilani with John Butler will do the review and report will be presented to Stakeholders.</p>

3. RESOURCES AND COSTS	
1. Overall Cost of the Project	£15,000
2. Direct and Indirect Commitment by Each Organisation (Resources / Costs)	<p>Upon invoicing Alia Giliani will be paid by Sheffield CCG £2,500 upon completion of each Pilot.</p> <p>Payments to all other HCPs will through their normal Payroll</p> <p>AstraZeneca will fund a fixed pilot fee per project site for Alia Gilani, Pharmacist in a mentoring role, which will last for 4 months per site and the total length of the project is 12- 18 months dependent on availability.</p> <p>The cost to Astra Zeneca will equate to £2500 per pilot site with a maximum of 6 Pilots at a total cost of £15000.</p> <p>Break down of Pilot Costs, £500 per clinic (x 3 = £1500) £500 For mentoring £500 For Review set up</p> <p>This investment in the project will be matched by the CCG in provision of practice based pharmacists for the project and protected mentoring access to HCPs who provided the existing Diabetes Service.</p>
3. Method for Monitoring and Recording Resources and Costs	John Butler and Jenny Stephenson will oversee the completion of the project and confirm that payment to Alia Giliani Mentoring Pharmacist should be made.
4. Arrangements for the Longer Term Implications of the Project	The project aims to help improve patient outcomes in each pilot practice in a sustainable way. It also seeks to build on Practice based Pharmacists knowledge and delivery of practice diabetes services. Each practice will have an opportunity to assess their current provision. Each Review will feed into a wider CCG assessment of opportunities to take learnings forward across the PCNs and wider CCG.

5. Constraints	The short, medium and long term impact of the current COVID-19 pandemic.
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4. GOVERNANCE ARRANGEMENTS	
1. Parties Consulted Prior to Initiating Joint Working Project and How Consultation was Conducted	Dr Jenny Stephenson Clinical Lead Sheffield CCG Dr Jackie Elliott Consultant Diabetologist Northern general Mr Gary Barnfield Deputy Director Medicines Optimisation (AHPs) Sheffield CCG
2. Method for Informing Patients of the Project	An Executive Summary of the Joint Working Agreement will be placed on the AZ UK website.
3. Decision Making Processes Within the Project	Within the remit and scope of the project, decisions will be made by the Joint Working Project Group.
4. Operational and Managerial Accountabilities	In the interests of transparency, it will be clear that John Butler <i>employed by</i> AZ UK Limited, pharmaceutical company, that markets products in the diabetes and cardiovascular therapy area. Alia Giliani a contracted Pharmacist is commissioned by this project to deliver the service. All other Members of the Project are employed by Sheffield CCG our Practices / PCNs in the Sheffield CCG Region.
5. Relationship to Existing Systems of Care in Primary and Secondary Care Sectors	The project will have an impact on Diabetes services within Sheffield. The relevant stakeholders will be made aware of the impact that the project will have.
6. Professional Indemnity and Liability Arrangements	Any material produced as part of this project must have the following declaration statement on it making AZ involvement clear: 'This diabetes Clinic is part of a Joint Working initiative between (the name of the pilot practice inserted here) and AstraZeneca UK Ltd' Any materials produced as part of this initiative for use external to the Project Working Group must be submitted to AZ nominated signatories to ensure compliance with the requirements of the ABPI Code of Practice prior to any use. Whilst participating in this Joint Working Initiative, AZ employees in a promotional role will not refer to the project in any

	<p>promotional calls nor use the project as a means to gain access for a promotional call or activity.</p> <p>Clinicians will remain accountable for all delivery of care to and decisions regarding all patients.</p>
7. Exit Strategy	<p>A formal review will take place between members of the project steering committee at the end of each Pilot, to assess progress against agreed targets and milestones. Amendments to the Joint Working Agreement can be made should agreed targets and milestones not be met by both parties. Conflict resolution: a process of mediation will take place to avoid escalation. All termination rights are set out in clause 16.</p>
8. Method for Highlighting Significant Problems	<p>A risk log will be maintained by the Project Manager where any risks are identified which lie outside the project scope these will be highlighted to the Project Managers and detailed to the Project Board. Subsequent decisions may mean changes to the project or early termination</p>
9. Adverse Event and Product Complaint Reporting Requirements	<p>Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. If any member of the Joint Working Project Board is made aware of an Adverse Event or Product Complaint with any AstraZeneca product, they shall report this directly to the AstraZeneca Medical Information and Patient Safety department by calling 0800 783 0033 or emailing: patientsafetyUKMC@astrazeneca.com</p>

5. MONITORING AND EVALUATION	
1. Monitoring and Evaluation of Project (Outcomes vs Objectives)	<p>The objective of this project is to improve long term Diabetes outcomes. This will be delivered by completion of clinical reviews across 3 clinics in each pilot focusing on</p> <ul style="list-style-type: none"> • Improvement in HbA1c, • Weight, • Blood pressure • Foot care • Dietary Advice • Cardiac Risk Assessment • Follow up engagement by the Patient's <p>The second arm of the project is Mentoring of Staff which will be reviewed at the completion of each Pilot.</p> <p>Each Pilot will build in to a project review at the end of the Project</p>

2. Method of Evaluating Patient Benefits on Completion	<p>Patient benefits will be evaluated using the following parameters:</p> <ul style="list-style-type: none"> • Improvement in HbA1c, • Weight, • Blood pressure • Foot care • Dietary Advice • Cardiac Risk Assessment • Follow up engagement by the Patient's
3. Learning Opportunities from this Project	<p>This project will give both parties an opportunity to gain valuable experience in setting up projects in partnership between the NHS and AZ.</p> <p>It will allow The PCN and CCG to take any learnings in service provision and training opportunities and role out across the wider NHS.</p> <p>There will be a review meeting at the end of the project to evaluate the project and identify any unforeseen benefits / issues that arose.</p>
4. Audit Arrangements	<p>Audit data collected by the Pilot Practice by. Anonymised results to be shared with AstraZeneca rfor the purpose of a written review of the pilot.</p> <p>Data Collection:</p> <ul style="list-style-type: none"> • Improvement in HbA1c, • Weight, • Blood pressure • Foot care • Dietary Advice • Cardiac Risk Assessment • Follow up engagement by the Patient's

6. DATA AND PATIENT PROTECTION	
1. List Interests of Partners in Relation	For Joint Working Agreements in particular therapy areas, include;

<p>to the Proposal, and Where These Coincide</p>	<p>'AstraZeneca UK Ltd are responsible for marketing: Forxiga (SGLT2) Type 2 diabetes mellitus Forxiga is indicated in adults for the treatment of insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise - as monotherapy when metformin is considered inappropriate due to intolerance. - in addition to other medicinal products for the treatment of type 2 diabetes.</p> <p>Type 1 diabetes mellitus Forxiga is indicated in adults for the treatment of insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥ 27 kg/m², when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy.</p> <p>Bydureon (GIp1) Bydureon is indicated in adults 18 years and older with type 2 diabetes mellitus to improve glycaemic control in combination with other glucose-lowering medicinal products including basal insulin, when the therapy in use, together with diet and exercise, does not provide adequate glycaemic control.</p> <p>Onglyza Saxagliptin (DPP4) Onglyza is indicated in adult patients with type 2 diabetes mellitus as an adjunct to diet and exercise to improve glycaemic control: • as monotherapy when metformin is inappropriate due to intolerance or contraindications</p> <p>Combination products;</p> <p>XIGDUO is a fixed dosed combination of metformin and dapagliflozin and it is available in two strengths of metformin •5mg dapagliflozin and 850mg of standard release metformin hydrochloride •5mg dapagliflozin and 1000mg of standard release metformin hydrochloride</p> <p>Qtern, Is a fixed dose combination of saxagliptin and dapagliflozin, is indicated in adults aged 18 years and older with type 2 diabetes mellitus: • to improve glycaemic control when metformin and/or</p>
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	<p>sulphonylurea (SU) and one of the monocomponents of Qtern do not provide adequate glycaemic control,</p> <ul style="list-style-type: none"> • when already being treated with the free combination of dapagliflozin and saxagliptin.
2. List Potential Conflicts of Interest (see Conflict of Interest Declaration at the End of the Document)	<p>Refer to Joint Working Agreement Section 13. For example:</p> <ul style="list-style-type: none"> • All data generated by the programme will be owned by Sheffield CCG • No data will be disclosed to any third party except on the explicit agreement of all parties • Patient confidentiality will be maintained at all times <p>Anonymised data will be shared with AstraZeneca as audits are completed</p>
3. Identify "Ownership" of the Data Generated by the Project	NHS Sheffield CCG
4. Identify "Ownership" of the Intellectual Property Generated by the Project	Data and information on this project will be supplied on the event of a Freedom of Information request to NHS Sheffield CCG'
5. Describe Access Arrangements for the Data, and Format	NHS Sheffield CCG
6. What use will the Data be Put To?	<p>Data within the project will be used to enhance the treatment of patients with Diabetes.</p> <p>The project may be written up for publication by either party upon notification of all parties involved</p>

Section 6 – Part 2

VI. DECLARATION OF INTERESTS

YES

NO

If Yes, qualify by inserting a tick in one box in column A and one in column B

A	B
Personal <input type="checkbox"/>	Specific <input type="checkbox"/>
Non-Personal <input checked="" type="checkbox"/>	Non Specific <input checked="" type="checkbox"/>

Signature  Date 27/07/2020

Signature _____ Date _____

Personal implies that you (or your spouse / partner) receive direct payment for services or hold shares in the relevant company concerned or a competitor.

Non-Personal implies that your unit benefits by receiving funding from the company.

Specific implies that you have undertaken work or given advice on other products made by the relevant manufacturer.