Collaborative Working Project executive summary

Project title	A collaborative working project with Health Innovation South West developing optimal engagement strategies for the uptake of Autoimmune type 1 diabetes (At1D) screening for Endocrine patients within Royal Devon & Exeter Trust
Partner organisation/s	**South West Peninsula AHSN LTD (T/A Health Innovation South West)** Vantage Point Pynes Hill Exeter EX2 5FD **Sanofi** 410 Thames Valley Park Drive, Reading RG6 1PT
Project rationale	Type 1 diabetes is a condition caused by autoimmune damage to the insulin-producing pancreatic beta-cells leading to severe endogenous insulin deficiency. Autoimmune type 1 diabetes accounts for approximately 5–10% of all cases of diabetes worldwide and in the UK. (Maahs et al, Endocrinol Metab Clin North Am. 2010 Sep;39(3):481–497). In the UK, around 25% of those with newly diagnosed type 1 diabetes present with life-threatening Diabetic ketoacidosis (DKA), with higher rates in the very young (up to 30% in those under 5 years of age) and in ethnic minority groups. (Besser REJ, Ng SM, Gregory JW, et al. Arch Dis Child 2022;107:790–795.) Diabetic ketoacidosis is a life-threatening but avoidable complication of diabetes mellitus requiring rapid assessment and is often managed in intensive care units. Some studies indicate that DKA at diagnosis is associated with adverse long-term glycaemia (Duca LM, Wang B, Rewers M, Rewers A. Diabetes Care. 2017 Sep;40(9):1249-1255.). It is now widely accepted that type 1 diabetes is characterised by three stages: • Stage 1: Initiation of the autoimmune process (presence of two or more islet autoantibodies); Importantly, currently early stage is associated with normoglycaemia. In children, stage 1 is associated with a 44% risk of progression to stage-3 within five years of developing stage-1. (Besser REJ, Ng SM, Gregory JW, et al. Arch Dis Child 2022;107:790–795.) • Stage 2: Persistence of type 1 diabetes-related autoantibodies with further loss of βcell function and development of dysglycaemia. In children, stage 2 is associated with a 75% risk of progression to a diagnosis of T1D within 4 to 5 years, and a lifetime risk nearing 100%. (Besser REJ, et al. Arch Dis Child. 2022-107(9)-790-795.)

	• Stage 3: Stage 3 type 1 diabetes with hyperglycaemia which meets ADA criteria. In the absence of early testing, most patients present in this stage. Although it is largely accepted within the clinical diabetes community that there are 3 stages of autoimmune type 1 diabetes, early detection and management of pre-symptomatic disease is not routine practice in UK diabetes clinical care. Current UK clinical practice suggests that islet autoantibodies are sporadically tested for in the general population, with widespread variability between centres and clinicians. Populations at higher risk of developing T1D include; those with associated auto-immune conditions, adults or children with a family history of At1D, people who may have been misdiagnosed with T2D or individuals with no known risk factors. **Project focus:** This 12-month collaborative project will develop, implement and evaluate the case-finding model for early identification of pre-symptomatic Autoimmune Type 1 Diabetes (At1D) within endocrine patients who have co-existing autoimmune conditions. The model will integrate clinical identification, testing pathways and tailored patient and provider engagement strategies to support equitable uptake of screening. Patient engagement has been highlighted as a potential barrier to early detection. This project will assess the optimal patient engagement strategies for uptake of At1D screening in the endocrine auto-immune population. Alongside testing engagement approaches, the project will test and evaluate the case-finding model to assess its feasibility, effectiveness, acceptability and equity in routine clinical practice. Findings will inform a scalable framework for wider adoption across the NHS.
Project period	Q4 2025 to Q4 2026
Project objectives	This 13-month project, delivered in partnership between Sanofi, Health Innovation South West (HISW) and Royal Devon University Hospital Trust (RDUH) and under guidance of the ABPI Code of Practice, aims to deliver benefits for patients and the health system. The specific aims are to: 1) Identify at-risk populations within the current endocrine service who have co-existing autoimmune endocrine conditions, by developing and applying a case-finding approach to enable early detection of pre-symptomatic At1D and improve patient outcomes. 2) Optimise patient and provider engagement strategies to increase knowledge and understanding of the importance of early detection, thereby supporting equitable uptake of At1D screening in these populations. 3) Evaluate the feasibility, effectiveness and equity of identifying and engaging these at-risk populations for At1D

	screening, generating insights to support sustainable spread and adoption. It is anticipated the collaborative working project will deliver the following benefits: Patients • Increased knowledge and understanding of type 1 diabetes through specialist input. • Reassurance for antibody-negative patients about their lower risk of developing type 1 diabetes. • Improved and increased access to testing • Earlier education and monitoring for antibody-positive patients, reducing risk of DKA and supporting better glycaemic control. NHS and Health Innovation Network • Evidence to inform decisions on integrating case-finding into existing autoimmune caseload pathways. • Insight into uptake levels from targeted patients, and insights on which engagement strategies are most effective & deliver equitable reach. • Earlier identification and monitoring of presymptomatic At1D patients is expected to reduce the likelihood of DKA at diagnosis, leading to fewer emergency admissions and unplanned care episodes. • Scalable strategies to support national adoption. Sanofi • Practical insights on the real-world implementation of case-finding for presymptomatic At1D • Improved corporate reputation with associated partner organisations • Sanofi has a product in At1D that has been granted a licence by the MHRA and currently under reimbursement review in 2025. This project will be completed by pooling resources at a total cost of up to £120,000 Sanofi indirect and direct cost = £63,000 (52%) HISW /NHS indirect and direct cost = £57,000 (48%)
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