NIHR RDN commercial eligibility & feasibility submission form

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Section B: The information in this section has been provided by the commercial company in the non-confidential section of the submission. While catergorised as non-confidential for the purposes of the RDN feasibility and eligibility process, the information is COMMERCIALLY SENSITIVE and should be managed as defined in the RDN business processes. It may be distributed to third parties involved in supporting the delivery of RDN feasibility and eligibility process WITHOUT the need for a formal RDN Confidential Disclosure Agreement, however the confidentiality terms of the Performance and Operating Framework for RDN Host or Partner Organisations remain applicable.

Full study title	A Phase 3b, Randomized, Double-Blinded, Placebo-Controlled Study to Evaluate Retatrutide Treatment in the Maintenance of Weight Reduction in Individuals with Obesity
Study protocol reference number	J1I-MC-GZQB

SPONSORSHIP & FUNDING

B4: Name of research sponsor:	Eli Lilly
B5: Is Research Funder different to above?	No
If yes, please specify:	
The name and organisation of the Chief Investigator is required to submit a request for the Study Resource Review service.	
B6: Name of Chief Investigator	N/A
B6a: Chief Investigator Organisation	N/A No identified LCRN or health board

APPROVAL

B6b: Select the type of approval you will be applying for	HRA Approval
B6c: Provide details of the ethical approval you will be applying for	
B6d: Explain why you will not be applying for ethical approval	

B6e: Date of approval submission	01/12/2024

PRODUCT INFORMATION

B7: Name(s) and class(es) of investigational product	Retatrutide
B9: Who is responsible for the development of the product?	Eli Lilly
B10: Is the study multinational?	Yes
B11: Phase of development	
N/A	No
I	No
II	No
III	Yes
IV	No
B12a: If this is a Phase IV study, is this at the request of regulators?	
B12b: Category of Medical Technology Study	
B12c: Is the study a regulatory follow up requirement?	

STUDY DESIGN

B13: What is the disease indication / target patient population for the study?	Chronic Weight Management
B13a: Is your trial recruiting UK subjects under 16 years of age?	No
B13b: If Yes, has a Paediatric Investigation Plan (PIP) been developed?	
B13c: If a PIP has not been developed, please give details why not:	
B14: Route of study drug (if applicable)	
B14a: Type of investigational product / GMDN classification	

Other

B15: Please briefly describe the treatment and (if applicable) the randomisation schedule. Please include details of all study related treatments including comparator drugs, other protocol specified treatment regimens and the ratio of treatment groups.	116 weeks; 80-week open label lead-in period, 36-week randomized (1:1:1) double-blind treatment period
B15a: Are the study drugs / comparators being provided or will they be reimbursed?	Provided
B16: Primary objective(s)	To demonstrate that reta MTD continued for 116 weeks is superior to reta MTD for 80 weeks followed by placebo for 36 weeks for % change in body weight from Wk 0 to Wk 116
B17: Secondary objective(s)	
B18: Full inclusion criteria	18 years or older Have a history of at least 1 self-reported unsuccessful dietary effort to reduce body weight Have a BMI ≥35 kg/m2 at screening (Visit 1). Are willing to undergo DXA
B19: Full exclusion criteria	Have a self-reported change in body weight >5 kg (11 pounds) within 90 days before screening (Visit 1) Have a prior or planned surgical treatment for obesity Have obesity induced by other endocrinologic disorders Have T1D, T2D or history of ketoacidosis, hyperosmolar state/coma, other types of diabetes HbA1c ≥ 6.5% Taken other medications intended to promote body weight reduction within 90 days before screening (Visit 1) (e.g., orlistat, phentermine/topiramate, etc.) Within 12 months before screening (Visit 1), received a GLP-1R agonist, GIP/GLP-1R, GLP-1/GCGR or GIP/GLP-1R/GCGR agonist (e.g., liraglutide, semaglutide, tirzepatide) Taken glucose-lowering medications, such as metformin, within 90 days before screening (Visit 1) NOTE: Use of SGLT2i for treatment of CKD or heart failure consistent with local labeling is permitted eGFR <30 mL/min/1.73 m2, calculated by CKD-EPI Cystatin-C equation (2012) Have had within the past 90 days acute MI, stroke, hospitalization for unstable angina, hospitalization for CHF Have any implants, hardware, devices, or other foreign materials in the measurement area that may interfere

	with imaging requirements If currently taking medications associated with significant weight gain, have changed dose within 12 months before screening (Visit 1). If not currently taking these medications, have stopped less than 3 months prior to screening (Visit 1). These medications include, but are not limited to tricyclic and tetracyclic antidepressants, such as imipramine, amitriptyline, and mirtazapine atypical anti-psychotics, such as chlorpromazine and thioridazine atypical anti-psychotics, such as clozapine, olanzapine, and quetiapine mood stabilizers, such as lithium, valproic acid, and its derivatives paroxetine, a selective serotonin reuptake inhibitor, or phenelzine, a monoamine oxidase inhibitor.
B20: Please provide details of any specialist expertise or training required for the study which might impact on site feasibility e.g. administration of psychological tests:	PI must have experience in treating patients with chronic weight management in routine practice. PI must have experience conducting clinical trials for chronic weight management. Must have access to staff who can complete CSSRS. Preferable access to registered dietician/ nutritionist.
B22: Does the study involve any investigations using ionising radiation (this includes examinations which would be considered standard care in this patient group)?	Yes
B22a: Does the study involve any additional investigations using ionising radiation not viewed as part of standard care, (please note there may be variation in practice between trial sites)?	Yes
B23: Are there any other study requirements / practicalities which might have an impact on feasibility? Please include details of any unusual assessments in addition to standard of care for this patient population.	DXA machine Sites that have access to either Hologic™ or Lunar™ whole-body DXA scanners to measure body composition MRI (AMRA) Siemens / Dixon-Vibe Required Software GE / Lava-Flex Required Software Philips / mDixon Required Software Stadiometer with ability to measure to 0.1 cm Electronic weight scale that measures in kg to 1 decimal place with a capacity to accommodate participants with class 2 and 3 obesity Automated (non-manual; automatically inflates and deflates) blood pressure equipment. Needs to be an

arm device, not wrist. Need large and extra large (full range of cuff sizes)

20-meter indoor hallway to conduct 6-minute Walk Test (6MWT)

SITE INTELLIGENCE

B24: In order for the NIHR RDN to best support your study, we need to understand how far you have progressed in the site selection process. Therefore please provide details of sites which you have already contacted about the study and their current feasibility status. This is important, so that we do not duplicate work or cause misunderstanding when we discuss your study with investigators.

Name of site/practice	Status	Investigator Name	Investigator Email Address	Investigator Specialty	Additional Information

B27: What is the care setting e.g. Hospital/ General Practice (also known as primary/community care) for the following:

B27a: Participant identification	Primary care
B27b: Participant recruitment	Primary care
B27c: Participant treatment and follow up	Primary care

SITE IDENTIFICATION

B28: How many sites would you like the NIHR RDN to identify	5
B30: What type of sites would be able to participate in the study (e.g. those with a specific patient population or pathway, those with specific expertise, primary care/secondary care/tertiary care)?	Primary care sites who have service level agreement in place with provider of DXA and MRI.

B31: Please feel free to provide the Network with any further specific information that you think is important when the NIHR RDN are identifying additional sites, e.g.:

B31a: Geographical location:

England	Yes
Northern Ireland	No
Scotland	Yes
Wales	Yes
B31b: Investigator's specialism:	Chronic weight management
B31c: Prescribing requirements:	
B31d: Other	
B32: Are there any additional feasibility questions which you would like to ask in addition to the NIHR standard site level feasibility questionnaire?	Yes
B32a: If so please list a maximum of 4 key questions.	Do you have a service level agreement in place with a vendor who can provide DXA and MRI? Do you have a minimum of 20 meter INDOOR hallway to conduct 6 minute walk test? Do you have access to registered dieticians?

TRIAL MANAGEMENT

B33: Study timelines	
B33a: Planned Final Protocol date	09/10/2024
B33b: Planned date to have site selection finalised in UK	08/11/2024
B33c: Planned FPFV (First Participant First Visit) in UK	17/02/2025
B33d: Planned LPFV (Last Participant First Visit) in UK	22/09/2025
B33e: Duration of study treatment	2 Years 5 Months Days
B33f: Duration of follow up	0 Years 1 Months 0 Days
B33g: Planned LPLV (Last Participant Last Visit) in UK	07/02/2028

B33h: Planned FPFV (First Participant First Visit) globally	17/02/2025
B33i: Planned LPLV (Last Participant Last Visit) globally	07/02/2028

RECRUITMENT TARGETS

B34: Is the study already open to recruitment in other countries?	No
B35a: If yes, have any issues with recruitment been identified?	
B35b: Please provide the global recruitment to date versus target	
B36: What is the target recruitment:	
B36a: In the UK?	75
B36b: In the EU (if applicable)?	N/A - UK only EU country taking part
B36c: Worldwide (if applicable)?	581
B36d: What is the minimum recruitment target for individual sites?	6
B38: If worldwide recruitment applies, is this competitive?	
B39: What is the maximum number of study sites being sought in the UK?	12

CONFIRMATION

B42: Please provide any additional information or questions you have below :	
The information provided in the submission will be treated as CONFIDENTIAL however it may be distributed to third parties without the need for a formal confidentiality agreement, to support site feasibility. NIHR RDN site level feasibility is based on the information supplied, the schedule of events and any additional information supplied that can be circulated without the need for a CDA.	