Study Title	Global Overweight and oBesE (GLOBE) Patient Registry, development and implementation of disease-specific: severity, quality of life and cost instruments.
Indication studied	Overweight and Obesity
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Funder:	Medialis Ltd

Amendment No:	**Date of Amendment:**
Amendment No:	**Date of Amendment:**

Confidentiality Statement

Role of Medialis

Medialis Ltd is responsible for: study design, conduct, management, data analysis and interpretation, manuscript writing and dissemination of results.

Role of Funder and Sponsor: Medialis Ltd

As the funder and Sponsor of the study, Medialis Ltd will have oversight of all study activities.

Protocol Approval

Protocol Title: Global Overweight and oBesE (GLOBE) Patient Registry, development and implementation of disease-specific: severity, quality of life and cost instruments.

Protocol Ref:	MED 63
Protocol Version:	Version 1.1
Protocol Date:	22 October 2025

As Chief Investigator, I agree to conduct the above study in compliance with the approved protocol and will adhere to the principles outlined in the Declaration of Helsinki, the Sponsor's SOPs, and other regulatory requirements.

I agree to ensure that the confidential information contained in this document will not be used for any purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay, that an honest, accurate and transparent account of the study will be given, and that any discrepancies from the study as planned in this protocol will be explained.

Date: 22 October 2025

Name: Dr Ravi Jandhyala

Title: Consultant Pharmaceutical Physician
Medialis Ltd

1. List of Abbreviations and Definition of Terms

The following abbreviations and special terms are used in this document.

Abbreviation or special term	Explanation
CI	Chief Investigator
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
HCP	Healthcare Professional
HRA	Health Research Authority
HRQoL	Health-related quality of life
ID	Identification
ICF	Informed Consent Form
PIS	Participant Information Sheet
QoL	Quality of Life
REC	Research Ethics Committee
RWD	Real-World Data
RWE	Real-World Evidence
SOP	Standard Operating Procedure
TMF	Trial Master File

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2. Introduction

2.1 Background, Clinical Manifestations and Comorbidities

Excess body weight, defined as a body mass index (BMI) greater than 25 kg/m², includes individuals classified as overweight (25–29.9 kg/m²), obese (≥30 kg/m²), and extremely obese (≥40 kg/m²) [1,2]. While these thresholds are widely used, evidence shows that adverse health, functional, economic, and psychosocial consequences occur across the entire BMI spectrum above 25 [3,4]. Even modest excess weight is associated with morbidity, impaired quality of life, and higher health care costs.

2.1.1 Clinical Manifestations and Comorbidities

Individuals with BMI >25 present with exertional dyspnoea, fatigue, musculoskeletal pain, and sleep disturbances, including obstructive sleep apnoea [3,5]. Gastroesophageal reflux, acanthosis nigricans, and mobility limitations are also common [6]. With increasing BMI, the risk of type 2 diabetes, hypertension, cardiovascular disease, osteoarthritis, asthma, and non-alcoholic fatty liver disease rises markedly [7,8]. Psychiatric disorders such as depression and anxiety are also more prevalent [4,9,10]. Importantly, visceral adiposity and inflammatory processes drive much of this risk, independent of BMI cut-offs [3,5].

2.2 Disease Burden and Quality of Life

Health-related quality of life (HRQoL) declines progressively with BMI. Even overweight individuals report diminished physical functioning, vitality, and sleep compared to normal BMI populations [11,12]. These effects worsen with comorbidities [13,14]. Psychosocial consequences, such as body dissatisfaction, stigma, and social withdrawal, are pervasive [10,15]. Studies consistently demonstrate lower HRQoL scores in obese and extremely obese individuals, particularly those with multiple chronic conditions [8,14,16].

2.3 Economic Burden and Resource Utilisation

Excess body weight imposes substantial direct and indirect costs. Direct medical costs include greater use of healthcare, medications, and treatment for complications such as diabetes and sleep apnoea [17,18]. Indirect costs include absenteeism, reduced productivity, and early retirement [4,6]. Even overweight individuals without

comorbidities incur higher expenditures than normal-weight individuals due to preventive care and weight management [19].

2.4 Rationale for this study

Despite evidence on the burden of BMI >25, few disease-specific instruments comprehensively capture its multidimensional impact. Existing frameworks often target obesity (BMI ≥30) or patients on pharmacological or surgical therapy [4,16]. Overweight and extremely obese populations are underrepresented, and economic and psychosocial dimensions are rarely integrated into severity staging.

This study therefore aims to systematically evaluate symptoms, comorbidities, HRQoL, and costs across the full spectrum of individuals with BMI >25, excluding those on GLP-1 therapy. Integrating clinician and patient perspectives will support the development of more inclusive severity measures and inform early intervention strategies.

3. Study Design

This observational study will recruit participants to contribute data to the creation of a Neutral/exhaustive List [20] of disease-specific characteristics and cost categories and associated cost values. The Neutral List is built on the recently espoused Neutral Theory, which seeks to promote accuracy and neutrality in construct development [20]. In order to generate the detailed cost categories, this study will use the novel Jandhyala Method [20].

3.1 Phase 1a – Development of the Disease-Specific and Quality of Life Measures for Overweight and Obesity

We will recruit up to 15 expert Health Care Professionals (HCPs) involved in the healthcare management and treatment of overweight and obesity, and 15 individuals with a BMI of 25 and above.

Using the Jandhyala Method, HCP study participants will be required to complete an Awareness Round (1) survey that utilises free-text responses pertaining to their understanding of the clinical manifestations of overweight and obesity. This will form the basis of the disease-specific measure to be developed. In parallel, individuals with a BMI of 25 and above will also be required to complete an Awareness Round (1) survey that utilises free-text responses to report their quality of life (QoL).

3.2 Phase 1b – Consensus Survey

Following the completion of the Awareness Survey, the research team will collate these free-text responses and create a comprehensive list of all items provided by study participants. HCP study participants will be sent a Consensus Round (2) survey to about their agreement or disagreement with the inclusion of the items in the disease-specific clinical manifestations list, while individuals with a BMI of 25 and above will be required to express their agreement with the Neutral List of Quality of Life and Cost Categories.

The Awareness Round will be opened for three weeks to allow the research team to analyse the data from Round 1 survey and finalise the Consensus Round (2) survey (CR2 Survey). The CR2 survey will then be open for two weeks, with prompting to participants after one week if not completed. In the event that there are limited responses, the CR2 survey will remain open for additional three weeks. Thus, CR2 will be open for a total of five weeks.

In summary:

i. Awareness Round (1) online survey (hosted on MIA App) to be completed by HCPs and individuals with a BMI of 25 and above.
ii. The research team will collate and code the responses from the Awareness Round (1) survey.
iii. Consensus Round (2) online survey (hosted on MIA App) – the Neutral List of items for the disease-specific instrument and the cost categories will be sent to participants, and they will be asked to rate how far they agree or disagree with the inclusion of these items.
iv. The research team will collate this information, grouping the data into relevant high-level categories (domains).

3.3 Phase 2 – the longitudinal completion of the quality of life tool BMI of 25 and above (patient registry)

Following the completion of Phase 1 (the development of the Obesity and Overweight Quality of Life (QoL) Instrument, we will reopen recruitment. We will aim to recruit a minimum of 100 participants to complete the QoL instrument. Participants will be asked to complete the QoL instrument at monthly intervals for at least 12 months. The research team will analyse the changes over time within and between groups.
Statistical methods for this will be finalised when the measure has been completed at the end of phase one by our biostatistician.

4. Study Objective

4.1 Phase 1 (Design and creation of Disease Specific instrument and QoL Instrument)

For this Phase, the Jandhyala Method [19] will be employed to elicit participants' responses to the following questions:

1. What are the symptoms, signs and comorbidities of having a BMI over 25?
2. How does having a BMI over 25 impact your quality of life?
3. What are the costs incurred by individuals due to having a BMI over 25?

4.2 Phase 2 (Prospective collection of QoL data)

The QoL instrument will be completed monthly by individuals with a BMI over 25, for a minimum of 12 months to explore changes in QoL over time. This will be hosted on the MIA App.

5. Study Population

In total, up to 30 participants will be recruited for this study. This will comprise up to 15 HCPs involved in the healthcare management of individuals with BMI over 25, and up to 15 individuals with BMI over 25. We will be recruiting participants globally.

Prior to commencing the Awareness Round Survey, all participants will complete an online informed consent form and a demographic questionnaire at the start of their involvement with the study.

5.1 Inclusion Criteria

To participate in the study, an individual with BMI over 25 must meet the following criteria:

1. Patient is aged ≥18 years at the time of survey completion.
2. Patient has a BMI over 25 (self-reported)
3. Patient is willing to participate in all study activities.
4. Patient is able to read, write, and converse in English.

Healthcare professional participant must meet the following criteria for inclusion in the study:

1. HCP is aged ≥18 years at the time of survey completion.
2. HCP is suitably qualified and involved in the healthcare management of patients with a BMI over 25
3. HCP is willing to participate in all study activities.

4. HCP is able to read, write, and converse in English.

5.2 Exclusion Criteria

A participant who meets any of the following criteria will be excluded from the study:

1. Participants do not have the cognitive capacity to provide informed consent.
2. Participants with severe co-morbidity that might affect study participation.

5.3 Overall study design and schedule of assessments

Participants for this study will be recruited through an advertisement of the study via social media platforms. We will also contact HCPs via publicly available professional networks and platforms. The PIS will be used. In addition, the snowballing recruitment method [21] will be used to aid study participants. This means, we may request study participants to tell other people who meet the inclusion criteria about the study.

Each individual participant (people with a BMI of 25 and above) will be offered £10 (or equivalent voucher amount) as compensation for the time participating in this study.

We are aware that there may be country variations and compliance requirements that may affect whether a participant is able to accept this compensation. Hence, we will adhere to each territories existing regulations with respect to compensating study participants, to ensure we are not causing any distress to participants. In addition, it is important to note that compensation will be provided after all study activities are completed. Given that we expect all participants to complete two surveys, not more than 1.5 hours over two months, we believe that the remuneration amount is appropriate.

For HCPs, their remuneration will be in accordance with the average fair market values across the industry.

For contact purposes, participants will be provided with the details of the core research team from Medialis Ltd, who will provide a specific study information sheet for their consideration. Participants will be able to contact the research team if they have any further questions or queries. If they wish to participate, the research team will provide all relevant information.

Informed consent will be documented electronically at the start of Phase 1. In addition, demographic information will also be collected during the Awareness Survey (Phase 1). The demographic questions will generate data will be from broad categories such as, medical history, social history, family history of overweight and obesity, gender, age, ethnicity, height and weight. Please see the interview guides and the demographic questionnaire for an indication of the data to be collected from study participants.

Scheduled events across the study and their relation to the study's timeline relative to a participant are further illustrated in Table 1.

Table 1. Schedule of Events

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	Informed consent demographic survey (Phase 1)	Awareness Survey (Round 1)	Consensus Round 2 online survey (Phase 2)	Debrief Check-in after study participation
Contact 1 *(Month 1)*	X	X		
Contact 2 *(Month 2 [2 weeks after final contact 1])*			X	
Contact 3 (*Optional)*				X

5.4 Removal of Participants from the study

A participant will be withdrawn from the study if they request it. The study documents will be updated with the information that the participant has withdrawn and the reason for withdrawal (if provided by the participant). Participant data collected prior to withdrawal will be used in an anonymised form; this information will be part of the information sheet and consent process. While participants can withdraw from the study at any time, they will not be able to withdraw their data if it has already been anonymised and combined with the rest of the study data.

Participants will be reminded that their participation in the study can be terminated at any time prior to, during, or following study contacts. Study contacts can be postponed, paused or terminated at the request of the participant.

5.5 Participant Confidentiality

All participants willing to take part in the study will automatically be allocated a participant identification number upon registration. The corresponding codes respective to participant names and other data will be stored securely (linked and anonymised), with only the Chief Investigator and delegated research staff approved by the Chief Investigator having access.

All data analysis and dissemination will be restricted to study IDs; participants will not be identifiable from the publication of quotations or study data. Only the direct research

team approved by the Chief Investigator will be able to link study data back to the individual.

5.6 Data Quality Assurance

The study is sponsored and conducted by Medialis Ltd. Additionally, the study will be conducted in accordance with GCP and GDPR regulations, and self-auditing within the immediate research team will take place throughout the study's lifetime.

5.6.1 Monitoring and auditing procedures

Medialis Ltd will permit study auditing if requested by regulators. Essential study documents will be held securely in an electronic Trial Master File (eTMF). Regular study meetings will be held within the research team and with the study Sponsor, to review and maintain Good Clinical Practice (GCP) in relation to data capture, analysis, and maintenance of regulatory folders. All research activities will be done without jeopardising patient confidentiality.

5.6.2 Source Data

All source data (survey responses and Consensus data scores) will be anonymised, replacing any identifiable information with a numerical participant identifier. The protection of all participants and any personal or professional individuals discussed during the study contacts will be of utmost importance.

Data from Consensus Round 2 (Phase 2) will be downloaded from the MIA App and stored on secure online servers located within the UK or Portugal. Databases which contain all identifiable data for recruitment, as well as data pertaining to the conduct of the study contacts and dissemination of study findings, will be stored on an additional password-protected cloud server accessible only to approved researchers from Medialis Ltd.

5.7 Record Retention

Depending on the recruitment method, Medialis Ltd will not have access to participants' details prior to them sending us their information. For self-identifying participants no person will have access to any of their identifying details prior to them contacting the research team. Where appropriate, individuals will also be invited to participate in the study.

The CI will retain a list of the participants and their identification code (enrolment log), data and all study-related documents. The archiving period will for five years after the completion of the study.

6. Statistical Analysis Plan (SAP)

6.1 Statistical Methods

6.1.1 Phase 1a – Awareness Round Analysis

- Free-text coding: Responses will undergo thematic coding by two independent researchers. Discrepancies will be resolved by consensus.
- Data reduction: Items will be grouped into preliminary domains (clinical manifestations, QoL impacts, cost categories).
- Descriptive statistics: Frequencies and proportions of responses by domain will be summarised.

6.1.2 Phase 1b – Consensus Round Analysis

- Agreement for each item will be summarised as the percentage of participants responding "agree" or "strongly agree."
- Items achieving ≥50% consensus will be retained.
- Consensus Index values will be reported with 95% confidence intervals (CIs).
- Subgroup analysis (HCPs vs patients) will be performed descriptively.

6.1.3 Phase 2 – Longitudinal QoL Analysis

- **Primary Analysis:**
  - Repeated-measures models will be applied (linear mixed-effects models for continuous outcomes).
  - Fixed effects: time, age, gender, baseline BMI.
  - Random effects: participant-level intercepts.
- **Secondary Analysis:**
  - Generalised Estimating Equations (GEE) for binary outcomes (e.g., presence/absence of reported symptoms).
  - Trend analysis across 12 months using regression with time as a continuous predictor.
- **Exploratory Analysis:**
  - Cost category data will be summarised by median and interquartile ranges.
  - Associations between costs and demographics (e.g., age, BMI strata) will be explored using non-parametric tests (Kruskal–Wallis, Mann–Whitney U).

6.2 Handling of Missing Data

- Awareness and Consensus Rounds: Non-responses will not be imputed. Percentages will be based on observed data.
- Longitudinal QoL data: Missingness will be examined (MCAR, MAR, MNAR).
- If data are MAR, multiple imputation (MI) using chained equations will be applied. Sensitivity analyses will compare complete case vs imputed datasets.

6.3 Subgroup and Sensitivity Analyses

- Subgroups:
  - Patients stratified by BMI category (25–29.9, 30–34.9, ≥35).
  - HCPs stratified by specialty (e.g., endocrinology, primary care, nutrition).
- Sensitivity analyses:
  - Re-analysis excluding participants with <50% survey completion.
  - Alternative consensus thresholds (≥60%, ≥70%).

6.4 Sample Size Considerations

- Phase 1: A maximum of 30 participants (15 HCPs, 15 patients). This sample is adequate for item generation under the Jandhyala Method.
- Phase 2: Minimum of 100 patient participants, which allows for sufficient variability in longitudinal QoL scores. While not powered for hypothesis testing, the sample is appropriate for exploratory mixed-effects modelling.

6.5 Interim Analyses

- No formal interim analyses are planned.
- Descriptive summaries of recruitment and baseline characteristics will be periodically reviewed for quality assurance.

6.6 Statistical Software

- All analyses will be performed in R (R Core Team, Vienna, Austria).
- Key packages: tidyverse (data handling), lme4 (mixed models), geepack (GEE), mice (multiple imputation), and ggplot2 (visualisation).

6.7 Presentation of Results

- Tables: Participant demographics, item frequencies, consensus percentages, longitudinal means.
- Figures: Line plots of QoL trajectories, forest plots for consensus indices, boxplots for cost categories.
- All estimates will be presented with 95% CIs.

6.8 Deviations from SAP

Any deviations from the pre-specified methods will be documented, justified, and reported in the final study report.

7. Ethical Requirements

7.1 Ethical Review

Ethical approval of the study protocol, the Participant Information Sheet (PIS), the interview guide, and the Informed Consent Form will be provided by the UK NHS Research Ethics Committee (REC). Furthermore, it is the responsibility of Medialis Ltd, according to local regulations, to keep the UK NHS REC informed of any substantial amendments to the protocol during the study period. The written approval from the REC, including study identification and the date of review, will be filed by Medialis Ltd with a list of the REC members, their titles or occupation, and their institutional affiliations. All correspondence with REC, including annual reports and final study reports, will be filed in the study's Trial Master File (TMF).

7.2 Ethical conduct of the study

The study will be performed following the recommendations guiding physicians in biomedical research involving human subjects that were adopted in 1964 by the 18th World Medical Assembly, in Helsinki, Finland, with later revisions, as well as the UK Policy Framework for Health and Social Care Research.

Medialis Ltd will comply with the requirements of the General Data Protection Regulations (GDPR) and follow HRA guidance in the application of GDPR in health and care research.

7.3 Participant Information and Consent

Each potential participant will be given adequate written information, regarding the objectives and what the study entails, including answering any questions the participant may have throughout their participation and sharing promptly any new information that may be relevant to their willingness to continue their participation in the study. Participants who do not possess the capacity to provide informed consent will not be included in the study.

Participants will be informed about the right to withdraw their permission for entry of their data into the study at any time. Furthermore, it is the responsibility of the research team to obtain signed informed consent from all participants before including them in the study. The Informed Consent form must be signed electronically before any study activities can take place.

The signed Informed Consent form will be retained electronically by the research team for possible future audits and/or inspections. The final version of the Participant Information Sheet and wording of the Informed Consent Form will be approved by the IEC and will not be changed without their approval.

7.4 Managing Potential Discomfort or Distress

Participants will be reflecting on how their weight has affected them, which has the potential to cause discomfort. To minimise this, participants will be reminded that they can postpone any study contacts or opt out of the research at any time without any

reasons required. There will be an option to have a debrief session with the participants, after the study, to ensure none of the study processes has caused them any discomfort.

7.5 Researcher Safety

The study will be conducted online. The study will be conducted via participants accessing questionnaires online as well as individual interviews. There are no direct physical concerns for researcher safety. As part of the support mechanism for researchers working at Medialis, there will be regular debrief sessions between the research team and the CI to address any concerns arising from the conduct of the interviews. All debrief sessions will be confidential and will not breach the confidentiality of the participant, as set out above and in the Participant Information Sheet.

7.6 Changes to Study Documents

Any proposed change to the approved final study protocol will be documented in a written and numbered protocol amendment. All amendments, including substantial changes to the protocol, will be submitted to appropriate ethical review for approval. A substantial protocol amendment will be signed and dated by the same parties who signed the final study protocol, as applicable. If changes to the protocol or study documents are substantive and impact upon Informed Consent given by participants before the change, re-consent from participants will be sought in line with GCP guidelines.

7.7 Timetable

The study will be initiated in October 2025 and will run for 24 months. This timeframe should allow for the recruitment target to be met and for participants to be able to complete all study processes.

7.8 Study Limitation

The main limitation that needs to be considered in this study is whether the result may be generalisable to other disease conditions and territories. While the aim is to create a disease-specific instrument, a QoL instrument, and an exhaustive list of cost categories associated with overweight and obesity, the data may not be applicable to other disease areas.

7.9 Final Study Report

The final study report for the study will be available on the Medialis Ltd website. The study will be registered with clinicaltrials.gov.

7.10 Publication Plan

Analysis of study data is aimed at publications in peer-reviewed journals, and/or presentation at academic and patient congresses/conferences. Published journal articles, and conference abstracts/updates may also be available via Medialis Ltd website, as appropriate.

7.11 Disclosure and Confidentiality

- All researchers employed by Medialis Ltd are bound to confidentiality clauses as part of their employment contract. Participant details will be processed per the above regulations and frameworks for health research and GDPR.

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