

Clinical Trial Design: Body Composition Assessments in Obesity



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Who are we? Worldwide at a Glance

Worldwide Clinical Trials is a mid-sized Clinical Research Organization (CRO) with global reach and scale for all clinical trial needs.

70+ countries, all regions

30 locations
Research Triangle Park, NC, USA Headquarters

3,500+ local therapeutic experts

Point for Differentiation Body Composition

- Preservation of lean muscle is paramount to healthy aging.
- Clinical outcomes often equate weight with wellbeing.
- Lean mass is more reflective of health and longevity.
- Variations in patient phenotype and differential drug effects require a robust analysis of body composition.
- **An informed drug development program (preclinical to commercialization) emphasizes product differentiation, measuring endpoints beyond body weight and BMI.**

Point for Differentiation Outcomes

- The FDA defines clinical benefit as the effect of an intervention on how a patient feels, functions, or survives.
- Clinical development plans must acknowledge the complexity and variability of obesity as a condition.
- Researchers must take an active stance against obesity/weight bias.
- **Assessments should include a battery of outcomes and endpoints to capture multiple areas of potential improvement (e.g., mental health, cardiovascular outcomes, lifestyle).**

Our Study Design Process Integrating Science, Medicine, and Operations

1	2	3	4
Antecedents	Landscape	Case Studies	Final Design
<ul style="list-style-type: none">• Physiology• Asset MoA• Indication• Pharmacology• Toxicology• Guidance	<ul style="list-style-type: none">• Approvals• Ongoing trials• Trends• Modalities• Study designs• Study metrics	<ul style="list-style-type: none">• Phenotypes• Dose regimen• Key endpoints• Sample sizes• Power• Differentiators	<ul style="list-style-type: none">• Schematic• GCP synopsis• GCP protocol• Reg Interface• Study metrics• Expenditures

Comparing Assessments Body Composition

	Weight / BMI	CT	Ultrasound	BE Impedance	DEXA
Accuracy / Standardized	++	+++	+	+	+++
Info on Muscle Quality	-	++	+++	+	++
Site Accessibility	+++	+	+++	++	++
Cost	+	+++	++	++	++
Harm for Patient	+	+++	+	++	+

Adapted from: Looijaard WGP, Molinger J, Weijs PJM. Measuring and monitoring lean body mass in critical illness. Curr Opin Crit Care. 2018 Aug;24(4):241-247

Comparing Assessments Outcomes

Strategic endpoints to synergize scientific rationale, clinical impact, and operational efficiency.

- Functional Mobility**
Walk Test, Sit to Stand, Step Test, Stair Test, Hand-Held/Knee Dynamometry
- Cardiovascular and Metabolic Health**
Liver (e.g., Fib-4, NAFLD Score), Kidney (e.g., eGFR, CKD), Biomarkers (e.g., A1c, Insulin, Lipids, Leptin), MACE
- Lifestyle and Mental Health**
SF-12/36, PHQ-9, EQ-5D, HADS, HAM-A/D, CSSR

Clinical Trial Landscape Ongoing Industry-Sponsored Studies in Obesity

- Rapidly evolving landscape across modalities, mechanisms of action, formulations, and phases of development.
- Consistent treatment duration, target enrollment, and sites.
- **Emphasizes tailored endpoints/operations for differentiation.**

Phase	#	Treatment (mo)	Enrollment	Sites
1	85	3	63	1
1/2	6	5	88	3
2	54	6	186	18
2/3	3	43	300	32
3	56	12	428	44
4	28	7	181	3

Accessed via TrialTrove on September 24, 2024. MeSH term = obesity. Status = ongoing. Sponsor = Industry. Median values shown.

Selecting a Patient Population Acknowledging Patient Phenotypes

	Reference	Tall	Short	Muscular	Inactive
Weight (kg)	70	70	70	70	70
Height (cm)	170	183	152	170	170
WC (cm)	85	80	93	76	97
SM (kg)	26.7	28.6	24.1	29.3	23.6

Contact Us

Our Clinical Research Methodology Team

- Team of MD/PhD scientists with discovery backgrounds.
- Engaged across therapeutic areas, modalities (e.g., small molecule, biologics, ATMP), and phases of research (1-4).
- Interaction with 17 FDA Divisions, EMA, MHRA, Health Canada across 25+ programs in last 3 years.



Ask us about our experience in other cardiometabolic indications (e.g., T2D, MASH).

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