



Imaging in Metabolic and Body Composition Trials

Perceptive is a leading provider of proven medical imaging services with extensive experience in musculoskeletal (MSK) endpoint assessments. When tackling the many challenges involved in MSK trial imaging, global clinical trial sponsors repeatedly turn to Perceptive for the right experience, people, processes, and technology to drive their MSK development program's success.

Here we review how Perceptive is uniquely positioned to deliver reliable imaging data to support your metabolic and body composition clinical development programs.

Changes in muscle / fat / body composition in various conditions:

Perceptive has extensive experience with disorders related to muscle and fat changes such as Diabetes, Sarcopenia, Duchene Muscular Dystrophy, metabolic dysfunction, and Obesity-related changes in body composition measures related but not restricted to muscle and fat changes either in the whole body or at specific anatomic locations. Typically, most of these assessments are quantitative (volume or mass) with some being semi-quantitative.

We have worked with various modalities including DXA, CT, and MRI to delineate changes in these various anatomical locations. We can work on intra-muscular fat assessments using MRI sequences as appropriate and partner with third-party vendors as needed to facilitate the successful implementation of the right protocols and derive endpoints. Our dedicated, in-house experts tailor sequences to achieve the desired outcomes in a standardized fashion which included direct communication with sites during initial protocol setup and robust QC to provide feedback.

Expertise you can Rely on

Gain access to Perceptive's MSK scientists, who deliver therapeutic and technical expertise in imaging modalities, protocol design, and standardizing image acquisition across global investigative sites to drive your clinical development program's success.

Some of the criteria/assessments we have supported for body composition trials are:

- ▼ Body Composition by DXA
- ▼ Cardiac safety (MRI or ECHO)
- ▼ VAT/ SAT assessments by DXA as well as CT or MRI
- ▼ Single and multiple slice muscle and fat segmentation (CT and MRI)
- ▼ fMRI
- ▼ Bone age (pediatric)
- ▼ Bone density (DXA BMD)
- ▼ Specialized MRI imaging (Dixon, diffusion-weighted imaging, etc.)
- ▼ Cardiac safety (MRI or ECHO)
- ▼ Liver, kidney, spleen or pancreatic volume
- ▼ Liver, kidney, spleen or pancreas fat fraction

Engaging KOLs and expert readers

Our flexibility in choosing MSK-experienced readers enables you to utilize virtually any KOL as an expert reader. We collaborate with you to identify the most reliable readers and optimal read model for your trial, balancing their read volumes, and ensuring low inter-reader variability to drive the highest quality imaging reads for your study.

Global operational support

Perceptive's operational model enables our client delivery teams to anticipate your study needs and scale our services to deliver quick and reliable continuity of service with efficient setup of sites, dedicated teams for QC support, and reduced imaging queries to meet your trial timelines.

With deep operational oversight delivered through MSK trial-experienced project managers, Perceptive delivers the flexibility and scalability trial sponsors need during all stages of MSK treatment development, helping them to overcome challenges and confidently tackle unexpected trial changes.

Contact hello@perceptive.com to learn how Perceptive can support your metabolic and body composition disorder clinical development programs.