

Imaging in Women's Health and Endocrinology 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 women's health and endocrinology clinical development programs.

Osteoporosis:

Perceptive has supported 70 osteoporosis/bone mineral density trials with various drug candidates and biosimilars and has extensive scientific and logistical experience to successfully support such trials.

Dual-energy X-ray Absorptiometry (DXA) and X-ray imaging are routinely supported to assess efficacy and safety endpoints as well as support eligibility criteria. Our staff has extensive experience with Osteoporosis research/imaging, and we consult closely with clients to provide feedback on DXA and X-ray-related endpoints and safety signals during protocol development or revisions to ensure these are adequately captured. We also have a network of KOLs we can leverage to advise clients as needed.

DXA-derived T-scores as well as vertebral fracture assessments are reported to sites to enable timely decisions. Intelligent eCRF design and automated results reporting as per the unique requirements for each trial are put in place to ensure efficiency. In addition, our team also provides support to address site-central discordance and works closely with sponsors and sites to resolve such issues. Our solutions deployment and scientific staff work closely with the sponsor teams both to ensure the appropriate parameters and readouts are captured in the data exports and appropriate exports are designed to support any regulatory submissions.

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 Osteoporosis trials are:

- ▼ Bone Mineral Density, T and Z score assessment by DXA
- ▼ TBS scores and bone quality
- ▼ QCT based finite element analysis

Bone Age Assessments in Growth Hormone Deficiencies

Bone age serves as a means of interpreting skeletal maturity, holding significant importance in the comprehensive assessment and guidance of individuals with short or tall stature, impaired or accelerated growth, and delayed or early puberty. This evaluation is particularly relevant in pediatric studies focusing on issues such as obesity or growth hormone deficiencies.

An X-ray of the hand and wrist are acquired and assessed by comparing it to the Greulich and Pyle Atlas. At Perceptive, we have extensive expertise in this field and a knowledgeable team of readers. Additionally, we have the advantage of utilizing automated bone age assessment software (BoneXpert) based on the requirements of the trial.

Some of the criteria/assessments we have supported for Bone Age trials are:

- ▼ Bone Mineral Density, T and Z score assessment by DXA
- ▼ TBS scores and bone quality
- ▼ QCT based finite element analysis
- ▼ Greulich and Pyle Bone age assessment (Reader and /or automated software based)
- ▼ Tanner Whitehouse and Fels using Bone age software

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 women's health and endocrinology clinical development programs.