

Imaging in Rheumatology 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 rheumatology clinical development programs.

Rheumatoid Arthritis (RA) and Psoriatic Arthritis (PsA)

X-ray and MRI-based assessments are used to support eligibility / stratification and / or efficacy / endpoints.

X-ray is sometimes used for eligibility by confirming presence of bone erosions or Juxta-articular bone formation (in support of deriving a CASPAR score for PsA). X-rays of joints in the hands and feet are used to derive scores for various criteria such as modified Van der Heijde Sharp (mTSS) scores and other variations as needed to support efficacy endpoints.

MRI imaging is used to support Rheumatoid Arthritis MRI scoring (RAMRIS), Psoriatic Arthritis MRI scoring (PsAMRIS) and in quantification of Rheumatoid Arthritis using MRI (RAMRIQ). To ensure consistency in positioning and image quality specialized hand positioners and templates are used. Additionally, MRI and ultrasound imaging (US) are employed to support inflammation in the joints such as in tenosynovitis etc.

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.

Perceptive has supported the medical imaging needs of over 60 RA and PsA clinical trials to date, including the use of the following eligibility / stratification / efficacy criteria / assessments:

- ▼ Erosions
- ▼ Juxta-Articular Bone Formation (JBF as part of the CASPAR criteria)
- ▼ Sharp score
- ▼ Van der Heijde modified Sharp score
- ▼ Genant modified Sharp score
- ▼ RAMRIS and PsAMRIS
- ▼ RAMRIQ (Quantitative RAMRIS)

Spondyloarthritis

Radiographic AS Axial Spondyloarthritis (AS) is specifically characterized by the presence of structural damage in the sacroiliac joints (SIJs) which are noticeable on X-rays. This damage typically becomes visible several years after the initial onset of symptoms.

In contrast, non-radiographic axial spondyloarthritis (nr-AxSpA) does not display conclusive evidence of damage in the sacroiliac joints when examined through plain x-rays, unlike ankylosing spondylitis (AS). Instead, the presence of damage can only be visualized using MRI.

Perceptive brings extensive expertise in managing clinical trials within this field, having supported over 20 Ankylosing Spondylitis trials to date. Our team collaborates with renowned global experts who serve as central readers for these trials, ensuring the highest level of precision and accuracy.

Some of the criteria/assessments we have supported for Axial Spondyloarthritis trials are:

- ▼ Modified New York score (mNY)
- ▼ ASAS OMERACT MRI score
- ▼ SPARCC for spine and SIJ
- ▼ Berlin Score
- ▼ FASSS scoring

Osteoarthritis

Imaging in osteoarthritis trials is of critical importance as the endpoints relate to a reduction in joint space narrowing at the frequently evaluated joints (knee, hip, shoulder, and hands) as well as changes in cartilage and bone parameters. In order to enroll the right subjects several assessments are done both for inclusion and exclusion based on the trial design. This requires technical and imaging expertise as well as clear image acquisition guidelines and training of sites to acquire consistent images for X-ray and MRI.

Perceptive had supported the medical imaging needs of over 35 osteoarthritis trials and understands the specific needs of these trials. For example, we provide special knee, hip, and hand positioners to sites and train the technicians to acquire the appropriate views and angles especially since Joint Space Width (JSW) is highly sensitive to the technique employed. MRI imaging in OA also requires dedicated protocol implementation on scanners and working closely with sites to provide timely feedback to optimize image quality.

Some of the eligibility / efficacy and safety criteria/assessments we have supported for Osteoarthritis trials are:

- ▼ KL grading
- ▼ Joint Space Width
- ▼ OARSI Scores
- ▼ Synovitis Scoring
- ▼ MOAKS/ WORMS /BLOKS Scoring and modifications thereof as needed per trial needs
- ▼ Quantitative cartilage and bone shape assessments (partner with Expert third party vendors as needed)
- ▼ Osteonecrosis, Subchondral Insufficiency Fractures (SIF) etc.
- ▼ Conformation of intra-articular knee injection

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 rheumatology clinical development programs.