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## **CLASSIC Clinical Trial: A Methods Study in Unexplained Back Pain**

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## ABSTRACT

Axial spondyloarthritis (AxSpA) is a type of inflammatory arthritis that primarily affects the spine including the sacroiliac (SI) joint located at the base of the spine. Over a lifetime, the AxSpA can lead to the fusion of the vertebrae and crippling effects on quality of life. This condition is subdivided into two forms: ankylosing spondylitis (AS) and non-radiographic axial spondyloarthritis (nr-axSpA). While AS is usually diagnosed using X-ray images that show irreversible bone damage, nr-AxSpA is more difficult to diagnose. In both cases, early detection of disease will best prevent disease progression and preserve quality of life. An additional form of imaging, magnetic resonance imaging (MRI), has been valuable in developing more effective AxSpA classification criteria by allowing earlier identification of inflammation within the spine. However, the classification criteria remain under scrutiny due to the lack of specificity in biological markers and physical examinations. The Classification of Axial Spondyloarthritis Inception Cohort (CLASSIC) study aims to validate the performance of the current classification criteria in a prospective cohort of patients presenting to rheumatologists with low back pain. The study achieves these goals by assessing individual subjects in a step-wise manner that blinds the site primary investigator (PI) to the subject's information.

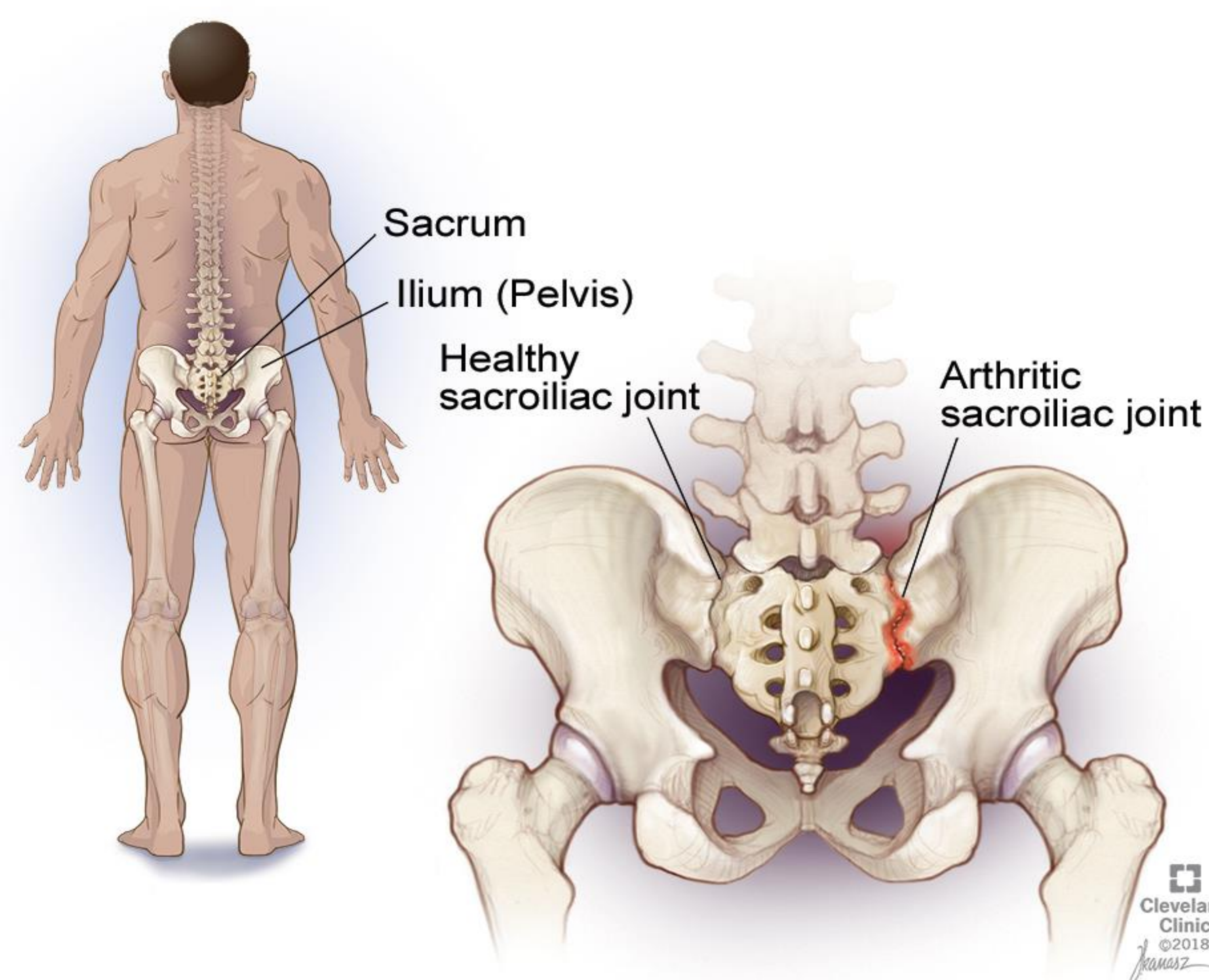


Figure 1. Diagram showing sacroiliac (SI) joint location and anatomy.<sup>3</sup>

## PURPOSE

1. Assess if current diagnostic criteria are specific enough to the condition while being able to reliably detect the disease.
2. Assess if education on reading MRIs improves assessment of sacroiliitis.

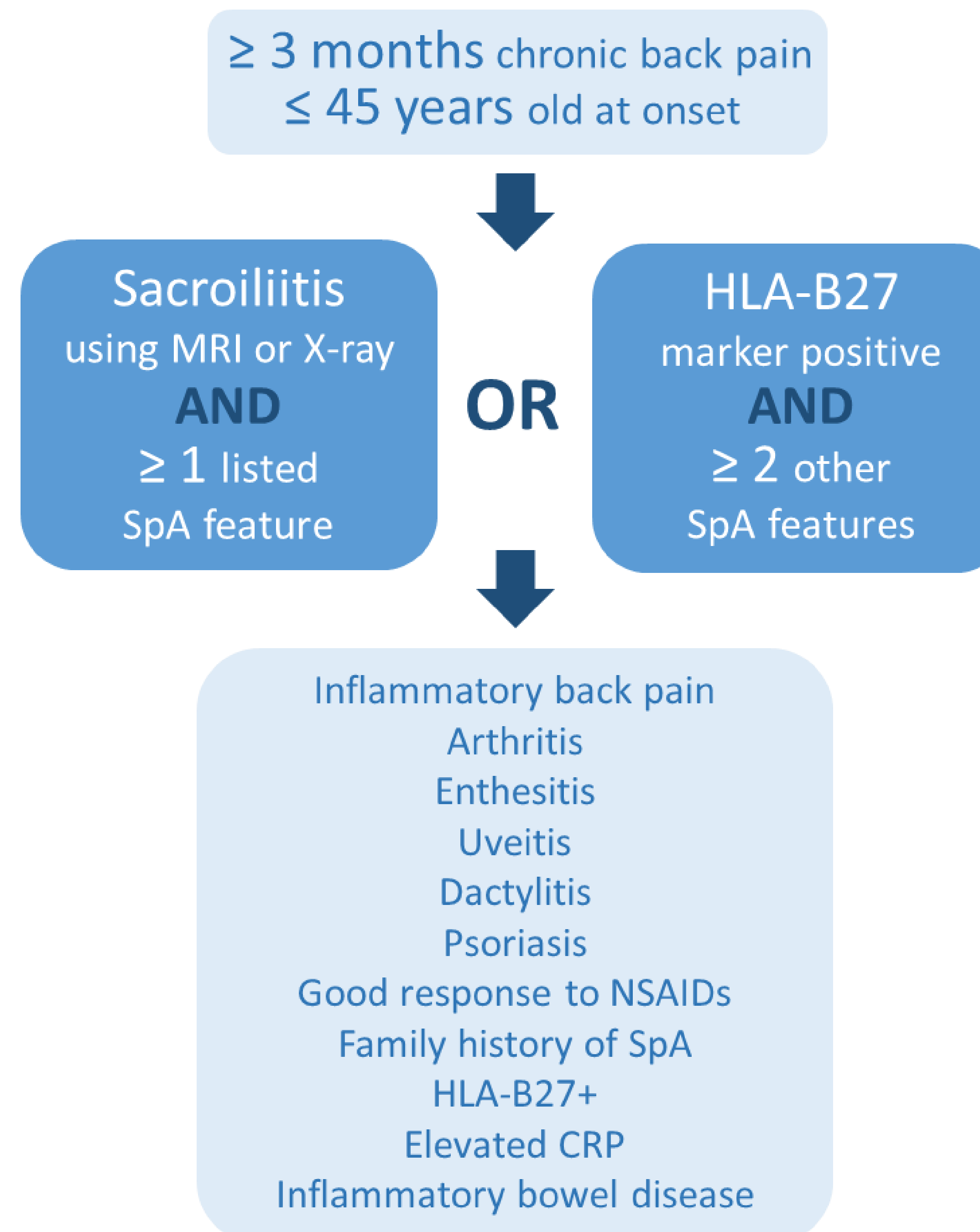


Figure 2. Assessment of SpondyloArthritis (ASAS) classification criteria.<sup>4</sup>

## STUDY METHODS

### Study Design

- Prospective observational study with follow-up at 5 years
- 500 people from 23 sites in North America
- 20 subjects from Cleveland Clinic

### Key Eligibility

- ≥ 3 months of undiagnosed back pain
- Pain onset at ≤ 45 years of age
- Able to undergo MRI scan

### Subject Exam

- 1) Physical exam (Flexibility, Pain, History) \*
- 2) Blood Draw Lab Tests (HLA-B27, C-Reactive Protein) \*
- 3) Pelvic X-ray \*
- 4) Pelvic MRI \*
- 5) Central Review of imaging \*

\* Site PI (Husni) recorded confidence in AxSpA diagnosis after each step

### Blinding

- Central review conducted by three external experts
- PI blinded to the information of subsequent steps before confidence assessment

## RESULTS

- Recruitment Statistics
  - 23 active sites
  - 6 sites have completed enrollment
- 401 participants have been successful in obtaining pelvic X-ray and MRI and being evaluated by rheumatologist in a step-wise algorithm
- Data obtained from these assessments will be used to inform the clinical dataset for classification

## CLINICAL IMPLICATIONS

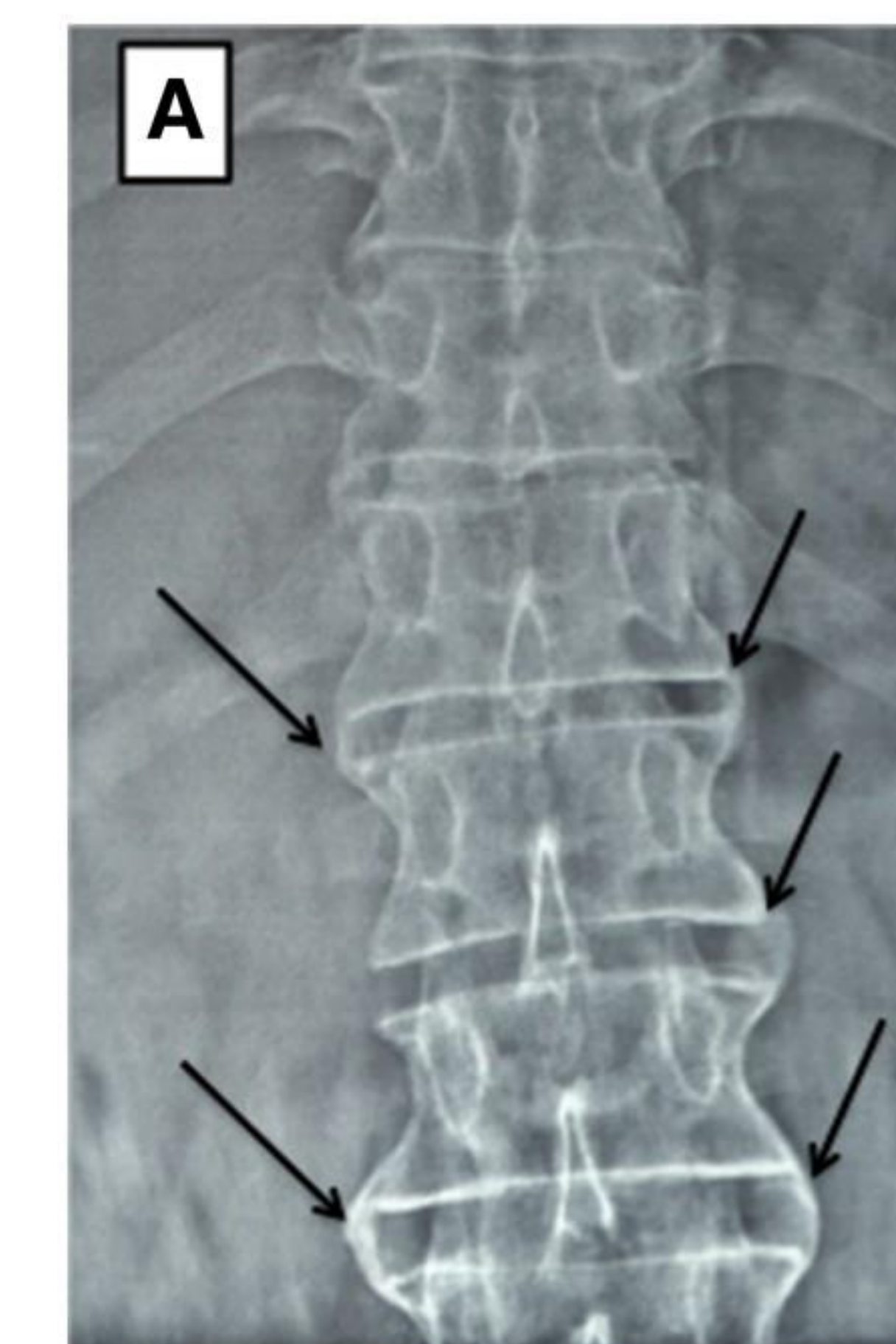


Figure 3. X-ray demonstrating spinal fusion characteristic of AS known as "bamboo spine."<sup>5</sup>

- No cure for AS, exists only symptomatic treatments
- Untreated AS can lead to the fusion of the vertebrae (known as bamboo spine) & loss of function
- Early diagnosis means earlier treatment leading to improved patient outcomes
- Early treatment preserves greater quality of life
- Applied Goal: Provide AS patients with better outcomes

## ACKNOWLEDGMENTS

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<sup>3</sup> Kanasz J. Healthy and Arthritic Sacroiliac Joint. 2018. <https://specialtycareclinics.com/blog/sacroiliitis/>. Accessed March 22, 2022.

<sup>4</sup> Adapted from Jans et al. 2013. Diagnostic value of pelvic enthesitis on MRI of the sacroiliac joints in spondyloarthritis. *European Radiology*. 24: 866-871.

<sup>5</sup> Figure 1 [Image]. In: R Sandal, K Mishra, A Jandial, A Khadwal, P Malhotra, Ankylosing spondylitis and bamboo spine, *QJM: An International Journal of Medicine*, Volume 111, Issue 12, December 2018, Pages 913-914, <https://doi.org/10.1093/qjmed/hcy158>

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