



## Clinical trial data sharing impacting patient care in Rheumatoid Arthritis

### BACKGROUND:

Rheumatoid arthritis (RA) is an autoimmune disorder, which primarily affects the joints and is characterized by inflammation and pain. RA most commonly affects the hands and wrists, but can also affect other parts of the body. There is currently no cure for RA, but treatment options have improved considerably in recent years with the development of new therapies and treatment strategies. One of these, the Treat-to-Target (T2T) strategy, aims to achieve a target of level of remission, or at least low disease activity, as quickly as consistently as possible.

### RESEARCHER QUESTION:

Dr. Ricardo Ferreira is an auxiliary researcher at the Nursing Center for Research, Innovation and Development in Lisbon, and also an invited researcher at the rheumatology department in the



University Hospital of Coimbra. Since completing his PhD in 2019, Dr. Ferreira is primarily focused on developing research projects focused in the fields of nursing, patient involvement, multidisciplinary team care and person based care.

For this study, Dr. Ferreira and his fellow researchers sought to understand the value of one of the key criteria used to determine remission: the patient global assessment. In this assessment, the clinician asks the patient to score from zero to ten the amount of burden that the patient felt in the previous week.

*“Clinical trial data is powerful, but it's also very expensive. By analyzing existing data, it's possible to uncover important new insights that aren't available from observational data or cross sectional data.”*

- Dr. Ricardo Ferreira

### FINDINGS

This dataset included a very large number of patients with different clinical characteristics, which allowed the research team to do multiple statistical analyses to clarify the question in different ways. The primary finding from this study was that a very considerable number of patients, more precisely 19%, fail to achieve remission solely on the basis of patient global assessments. Additionally, the team determined that there was no difference in radiographic outcomes between patients who were classed as “near remission” and those classed as in full remission.

### IMPACT

Following on from these results, the research team has proposed a new model of care: the dual target strategy. The proposed new model would consider both patient reported outcomes and more objective measures, like inflammation status or tender joint counts, in the definition of remission. Both would have equal importance and help to guide both immunosuppression and nonpharmacological care. This proposal has received attention from key stakeholders in the RA research community.

## RESEARCH PROCESS:

To evaluate the long-term predictive value of patient global assessment regarding radiographic damage and physical function, the research team requested access to 11 studies held on the Vivli database of clinical trial data. These trials included individual patient data (IPD) from more than 6000 participants; all tested the efficacy of biological drugs and used as a hard outcome the radiographic damage, which provided key data for the team's assessment.

## NEXT STEPS:

READ MORE

[OP0189 remission criteria guiding immunosuppressive therapy in RA: Which is best fitted for this purpose? \(BMJ\)](#)

[Interview with Dr. Ferreira](#)

[Find out more about requesting data from Vivli.](#)