

New points for therapeutic drug monitoring in people with rheumatic disease

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Therapeutic drug monitoring (TDM) refers to the principle of using blood concentrations of biopharmaceuticals to guide therapeutic decisions. EULAR—the European Alliance of Associations for

Rheumatology—has developed a set of new "points to consider" to support TDM in people with inflammatory rheumatic and musculoskeletal diseases (RMDs). This publication appears in the May 2022 issue of the *Annals of the Rheumatic Diseases*. The new points are evidence- and consensus-based statements addressing the clinical utility of TDM in RMDs. In general, proactive use of TDM is not recommended, but reactive TDM could be considered in certain clinical situations.

Interest in TDM is increasing in rheumatology. This is supported by a growing body of evidence that TDM could be useful in several clinical situations, such as loss of response to therapy, interpretation of side effects, and to help determine dose adjustments. However, there are also knowledge gaps around the potential use of TDM, and many rheumatologists are unaware of the pharmacokinetic properties of the biopharmaceuticals that they prescribe.

Although biopharmaceuticals typically have a dose recommendation in their label, research has shown that individual patients have variation in the levels of the drug found in their blood. This finding suggests a potential benefit for dose optimization. However, the new points highlight that—despite an association with clinical response—the use of blood concentrations to guide dosing is not recommended due to the lack of an identified optimal range for most biopharmaceuticals in most indications.

The new EULAR points-to-consider were developed by a multidisciplinary task force from eight European countries, with [health care professionals](#) from rheumatology, bioanalytical science, health economics, and clinical pharmacy. There was also a partner from EULAR's EMEUNET program, and three patient representatives. The work was completed in line with EULAR standardized operating procedures. All information included in the final paper was based on a

systematic literature review and expert consensus.

Overall, six overarching principles and 13 points were formulated. The principles define two broad categories of TDM: proactive (scheduled testing irrespective of clinical situation) and reactive (testing in response to particular scenarios). The principles also reinforce key underlying pharmacokinetic and pharmacodynamic principles, which are relevant to all biopharmaceutical classes. An important consideration is that TDM should be part of a shared decision-making process between the patient and health care professionals, incorporating the patient's individual experiences and preferences.

The "points to consider" highlight the clinical utility of the measurement and interpretation of biopharmaceutical blood concentrations—as well as anti-drug antibodies in specific clinical scenarios. They stress that measurements should be performed in a validated laboratory, preferably using a consistent assay over time when measuring anti-drug antibodies.

This new publication highlights the potential clinical utility of the measurement and interpretation of biopharmaceutical blood concentrations and anti-drug antibodies, but places this alongside factors that influence these parameters such as dose, administration interval, [body weight](#), methotrexate cotreatment, disease activity, and adherence to treatment.

As the field rapidly progresses, it is anticipated that more data will become available, which may prompt an update of these points to consider in the years ahead. Future research should focus on providing evidence on the effectiveness and safety of TDM, as well as a robust economic evaluation of its utility in patients with various RMDs.

More information: Charlotte L. M. Krieckaert et al, EULAR points to consider for therapeutic drug monitoring of biopharmaceuticals in

inflammatory rheumatic and musculoskeletal diseases, *Annals of the Rheumatic Diseases* 2022. [DOI: 10.1136/annrheumdis-2022-222155](https://doi.org/10.1136/annrheumdis-2022-222155)

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