

European Medicines Agency
EudraCT registration team
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CHRU de TOURS
10/27/2021

Dear EudraCT registration team,

Acting on behalf of the sponsor, I would like to inform you that the results of the trial referenced below have not been published in EudraCT.

EudraCT Number	Full title of the trial	Sponsor name
2014-000859-91	Relation entre la déplétion des LYmphocytes T et la réponse clinique au RITUximab dans la polyarthrite rhumatoïde.	CHRU de TOURS

Results are not yet available for several reasons:

- The last visit of the last visit (LVLP), theoretically scheduled for March 2020, was conducted in December 2019 without the Sponsor being informed
- The COVID pandemic has had a strong impact on the Sponsor's research activity. All studies were suspended in March 2020 and then a phased resumption was implemented beginning in June 2020. The LYRITUX study was not a priority.
- As a result, the quality control was finalized late and the base freeze was achieved in March 2021.
- Bioassays also started late. And some analyses are still pending due to resource problems (lack of equipment due to COVID, just-in-time activity of laboratory technicians with priority given to analyses related to COVID) or collaborations to be contracted.
- It should also be noted that the coordinator was abroad for a twelve months temporary mission between september 2019 and august 2020. The research project associated with this mission has kept the coordinator very busy since its inception and is still going on.

At this stage of the project, we are starting to get feedback from the first biological assays. The results of the rituximab concentrations were returned on 31/08/2021. There are still blockages and the full results will not be obtained by the end of the year.

The results will be posted in EudraCT as soon as possible.

Yours sincerely,

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