

(January 2021)



Latest news from

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## General

Dear All,

Please take the time to find the latest news and updates of our R-LiNK project at the beginning of an exciting year in 2021.

Looking back at the year 2020, there is no denying the fact that the Covid-19-pandemic affected all study processes. Processes were delayed, shipping of material impossible, recruiting processes stopped, meetings were postponed. It was even decided to pause the study for a while until all necessary processes could continue without limitations. All work packages had to cope with the national restrictions and international difficulties.

Thank you everyone for doing your best to stand through these unforeseen hurdles and keep processes running. We still strongly believe in the significance of the work all of you are investing time and energy in. Let us strive even harder to learn more about lithium therapy and increase the quality of life for numerous patients with bipolar disorders.

Let us remind you that the first patient was included in January 2020 in Dresden. Delays due to different reasons, with the pandemic being an important factor, hindered other centres from opening for recruiting. Thus, a request to extend the duration of the recruiting period, originally planned to last one year, has been submitted in each country. The Executive Committee is discussing also the request of an extension of the whole R-LiNK project duration to the funder. The advisory board members offered their support by writing a letter to add to the extension request. The consortium is now focussing on the preparation and submission of the second periodic report to the European Commission (1 July 2019- 31 December 2020).

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## General

Besides all difficulties, in the course of the year and especially in the last quarter of the year eight centres were able to continue or start recruiting processes. We are glad to announce that in total **25 patients** have been included! This is good news and hopefully within the extended time frame the number we aim for can still be reached.

More good news: The first Lithium-MRI-Scan was performed on 18<sup>th</sup> December on a subject in Dresden!

Due to the pandemic, the third R-LiNK annual meeting that had originally been scheduled for March 2020 in Milan and which was postponed to November 2020 had to be cancelled in the end. As a replacement, a virtual meeting was held on November 10<sup>th</sup>. Among the invited were R-LiNK consortium members, R-LiNK Scientific Advisory Board members, R-LiNK Ethics Advisory Board members and EC Project Officer. The meeting was a great success. We heard presentations on achievements, progression of tasks, hurdles and future tasks from all work packages and had fruitful discussions on the publication policy and on the extension request.

**Save the date:** We are very much hoping for a face-to-face meeting to take place in Milan in March 2021! Please save the date 18<sup>th</sup>-19<sup>th</sup> March already. Whether it might be postponed or replaced by a virtual meeting will depend on the situation.

Stay safe and healthy and happy 2021 to everyone!

Below, you will find a short overview from each work package.

All the best

WP leaders and Project Management Team

**NOTABLE. Remember if you need important documents such as SOPs, reports, ExCom Minutes, Protocol etc. you will find them on the project website and extranet <https://rlink.eu.com/collaborative-research-project/>**

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## WP1

In 2020, there was a change of staff: Barbara Caignard left for a new position. The new project manager is Delphine Smagghe (INSERM) who now is leader of WP1. Delphine and colleagues so far organised two ExCom meetings on October 2nd and December 4<sup>th</sup>. Reporting: The first periodic report was accepted end of 2019 and payment was distributed, now the second periodic report is due in January, covering July 1st, 2019 – December 31<sup>st</sup>. The next steps are to support the extension request, to implement the central database and to open the last centres., 2020. All work packages report on their activities in the past one and a half years, the results will be coordinated and controlled by WP1.

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## WP2 / WP3

So far, the first data exports have been performed to test and valid the data pipelines with WP7. Unfortunately, there were some significant delays to initiation of participant recruitment: For some sites the delays occurred due to problems in obtaining approvals to start recruitment. Furthermore, many study centres received the approval to begin recruiting shortly before the outbreak of the Covid-19 pandemic in Europe. WP2 and WP3 had to cope with delayed site initiations as well, concerning questions about the protocol's compliance with the GDGR, in other cases legal issues about contracts needed to be sorted out. All unified forces of the clinical resources were mobilised on the epidemic between March and June 2020; thus, recruitment was halted for approximately 6 months. In addition, lockdowns sat up in some countries (France, UK, Germany, Spain). Nonetheless, almost all sites are open for recruitment now and in total 25 patients were included this year.

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## WP2 / WP3



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## WP4

A side meeting took place in April 2020 with people involved in the scanning process. The participants discussed the potential pitfall, the presentation of sanity and the quality control. Standard operating procedures (SOP) for MRI datasets (WP4 and WP5) were made accessible in the centralized database in collaboration with WP7. In November 2020, the first MRI data was received for Paris, Besançon and Dresden. The sanity check and the quality of the data were satisfactory.

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## WP5

All centres implement the protocol, i.e. all WP5 sites are in a position to acquire data for R-LiNK. In addition, the first Lithium scan was performed on a patient on the 18<sup>th</sup> December in Dresden. There has been a lot of development work, which is of great interest from physics perspective. UNEW is preparing an abstract to submit to the International Society for Magnetic Resonance in Medicine.

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## WP6

Due to the all-over delay in recruiting, the tubes are about to expire in all the centres. New tubes needed to be acquired and sent to recruiting centres along with new labels. The refill of tubes will be organised in different shipments, considering the delay in recruitment, with the possibility to change plans according to the recruitment rate of each centre. WP6 is also working on finalisations of other contracts (MTA with Biobank Västland with CRO) and Ethics approval (letters for handling biological materials from Paris and Munich).

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## WP7

The central database is still in the pilot phase, the quality of the data is currently checked.

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## WP8 / WP9

The publication policy had been discussed at several meetings since the criteria for authorship were unsatisfactory and raised concerns. It was decided via voting between two options. Different criteria will be applied for general papers as opposed to more specialized papers.

Julia Henke is now responsible for WP 9 in Dresden. If you have any questions, concerns or propositions (regarding WP9): [julia.henke@uniklinikum-dresden.de](mailto:julia.henke@uniklinikum-dresden.de)

This newsletter will hopefully be one of many to keep all partners updated in the future. To ensure this, Julia aims to intensify the personal connections with the WP leaders. Nonetheless, we are relying on your support, so please keep us updated on any news and changes!