

Publishable Summary

Before March 2020, the DPMS recruitment was on a very positive track and all indicators were green as to the target of 900 randomised participants included by the end of June. Unfortunately, COVID-19 brought recruitment to a complete halt.

Different measures were discussed on how to continue the study, and a delay of 6 months was granted for completing recruitment, originally planned to be completed by June 30th 2020. A further facilitating measure granted in the last protocol amendment was making optional the 2nd scan for arm 1 and the corresponding visit, as well as the 13 month visit. These measures would have allowed to reach 900 randomised participants by December 31st 2020. This plan implied the last follow-up visit end of August 2021, and just 4 to 5 weeks to deliver the full analyses to IMI. Despite an extremely strict timeline, we were ready to engage in the challenge as the prize would have been the recruitment of 100% of the expected study population.

However, it has become clear in the past few weeks that the continuing COVID-19 crisis throughout Europe had almost completely dried up recruitment, which was as low as 5 new participants in the whole month of August – and as you are aware the situation is not expected to improve any time soon. Thus, even the new deadline of December 31st 2020 is not going to help recruitment significantly, and the target of 900 randomised participants is completely unrealistic under these circumstances.

The above considerations forced us to decide discontinuing recruitment between September 30th and October 30th 2020. As the total number of at least 810 randomized participants was reached on September 30th, recruitment is extended in October 2020. In any case, recruitment will not extend beyond October 30th 2020. Patients recruited after the closeout date will no longer be accepted in AMYPAD DPMS. Participants already included in the study will continue to be followed as scheduled.

This stop at the end of October will allow sites focusing on the follow-up visits, and on cleaning the data and support the analysis process.

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