

16<sup>th</sup> March 2021

To Whom It May Concern,

**Study title: Paramedic Analgesia Comparing Ketamine and Morphine in trauma: PACKMaN**  
**IRAS Project ID: 266748 / 1003404**  
**EudraCT number: 2020-000154-10**  
**Amendment Ref: Substantial Amendment 03**


Please find attached the following amended documents for review for the above-mentioned trial. This amendment is to increase the IMPD shelf life to 24 months following the completion of 12 month real-time stability tests.

Document	Version	Date
Annex 2	N/A	-
IMPD – clean version	2.0	15/03/2021
IMPD – tracked changes version	2.0	15/03/2021

We would also like to provide a non-substantial update to confirm that, as Sponsor for this trial, we have conducted a risk assessment for concomitant use of a COVID-19 vaccine with ketamine, morphine, naloxone and midazolam. Our assessment is that a COVID-19 vaccine given to a trial participant is considered a simple concomitant medication with no interaction that requires advice on timing of the vaccine or other aspects.

Please do not hesitate to contact us should you require any further information.

Kind regards,



Charlotte Scomparin  
Trial Manager