

Information regarding changes to Clinical Trial Application processing times

Processing times may be extended for new Clinical Trial Applications and Substantial Amendment Applications

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New Clinical Trial Applications

Please note that there may be a delay in processing times for new Clinical Trial Applications (over 60 days).

Substantial Amendment Applications

Please note that the principle of silent approval Substantial Amendment applications still applies. This means that the sponsor may implement the changes if the Regional Ethics Committee has approved the substantial amendment, and NoMA does not oppose the amendment within 35 days of receiving a valid application (in accordance with the [Norwegian Regulation for Clinical Trials of 30-10-2009, § 5-1](#)).

Applications for COVID-19 studies

We kindly request that you contact NoMA prior to any submissions for applications relating to COVID-19 studies so that we may prioritise the processing of these. Please send an email to klut@legemiddelverket.no and ensure that COVID-19 is included in the title of the email.

This information will be updated when processing times return to normal.

Contact

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Skriv ut

