



REPUBLIC OF CYPRUS

MINISTRY OF HEALTH

PHARMACEUTICAL SERVICES
NICOSIA 1475

Ref.: Ph.S. 21.6.16, 5.13.2.2
Tel.: 22-608-695
Fax: 22-608-669
E-mail: clinicaltrials@phs.moh.gov.cy

March 5, 2021

ENGLISH TEXT

Via electronic mail

To Sponsors and Applicants of Clinical Trials

Subject: Electronic Submission of Clinical Trials Applications (CTAs) on medicinal products for human use

The Drugs Council wishes to inform you that submissions of initial applications and applications for substantial amendments of clinical trials with all necessary documents (CTA dossier) are to be submitted to the Validation Unit of the Pharmaceutical Services in electronic version via the e-mail address submissionscy@phs.moh.gov.cy

All electronically submitted documents, including the application form and the cover letter, must include a scanned or an electronic signature certified through approved trusted service providers.

It is also reminded that the Drugs Council requires for the Protocol Synopsis to be submitted in Greek Language and the Labeling in Greek and or English language.

Additional and other documents for clinical trials (e.g. DSURs, USMs, CSR etc.) will also be accepted via the above e-mail address.

All applicants are encouraged to exclusively follow the aforementioned procedure which will be in place until the implementation of the new Regulation (EU) No 536/2014 on clinical trials on medicinal products for human use, and the repeal of Directive 2001/20/EC.

For more information on clinical trials you can contact the Pharmacovigilance and Clinical Trials Department via e-mail clinicaltrials@phs.moh.gov.cy

This circular has been uploaded onto the Pharmaceutical Services website www.moh.gov.cy/phs.



Helena Panayiotopoulou
Act. Director Pharmaceutical Services
Registrar Drugs Council