Saatja: Chevalier, Aleksandra <Aleksandra.Chevalier@fortrea.com>
Saadetud: 08.02.2024 13:48
Adressaat: TA Info <info@terviseamet.ee>
Teema: Safety reporting requirements for Medical Devices clinical trials in Estonia
Tähtsus: Kõrgeim

Dear Sir/Madam,

Hope this email finds you well.

Could you please confirm if the provided information (in green color) for Medical device clinical trials in Estonia is correct.

· Domestic USADEs occurring within study (yes/no)? Yes
· Foreign USADEs occurring within study (yes/no)? Yes
· USADEs from other studies with same study device / Cross-reports (yes/no)? No
o USADE Reporting Form: Clinical Investigation Summary Safety Report Form
o USADE Reporting Method: Electronic
o USADE Reporting Format: Electronic
Electronic reporting destination:
· Additional/Exceptions to expedited 7/15 USADE reports? (Yes/No) if yes, please see special reporting requirements: Yes - Serious public health threat: 2 days. Death or UNANTICIPATED serious deterioration in state of health: 10 days. Others: 30 days
· Periodic Line Listing required? (Yes/no) if yes, please confirm: No
o Frequency for Line Listing: NA
o Reporting Timeline for Periodic Line Listing (days after DLP) NA
o Periodic Line Listing Reporting Method (e.g. e-mail, N/A, etc.) NA
o Periodic Line Listing Format: NA
Destination for electronic Line Listing: NA
· Annual Report required? (yes/no) if yes, please confirm: No
o Reporting Timeline for Annual Report (days after DLP) NA
o Annual Report Reporting Method (e.g. courier, CESP, email etc) NA
o Annual Report Reporting Format (e.g. paper, CD-ROM, pdf, eCTD etc) NA
Destination for electronic Annual Report submission: NA
* Periodic Report Special reporting requirements: NA
o Translation required for safety reports? No
o Translation requirements - Language and report/information to be translated? (if yes, please specify the language) NA

Thank you in advance for your time and collaboration

Best Regards,

Aleksandra Chevalier, MPharm
Drug Safety Associate, Drug Safety

E: fortrea.comFortrea Development Ltd