

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

FortreaThis e-mail may contain confidential, proprietary, or protected information - including protected health information - that is meant to be viewed only by the intended recipient or company. Any unauthorized review, use, copying, downloading or disclosure is strictly prohibited. If this e-mail is not intended for you, or if you have received this e-mail in error, please notify the sender immediately. Do not forward it to any further recipients and permanently delete this e-mail and all attachments. If you have questions or concerns, please see our privacy policy on Fortrea.com