DOCUMENTS REQUIRED FOR THE AUTHORIZATION OF A CLINICAL TRIAL

For a new clinical trial application (CTA), the following documentation is required:

In hard copy and in CD-ROM:

1. Cover letter with the contents set out in section 2.3 of CT-1, ***in Greek***
2. Receipt of confirmation of EudraCT number
3. Clinical Trial Application form, ***in Greek***
4. If the applicant is not the sponsor, a letter of authorisation enabling the applicant to act on behalf of the sponsor
5. List of Competent Authorities to which the application has been submitted and details of decisions when issued
6. Proof of fee payment[1]
7. Summary of the protocol, ***in Greek***
8. Protocol with the contents set out in section 2.5 of CT-1, ***in Greek***
9. Certificate of agreement between sponsor and investigator
10. Brief and recent CV of the principal investigators for all investigational sites the clinical trial is conducted in
11. Informed consent form, ***in Greek***

Only in CD-ROM:

12. Investigator's Brochure (IB), or document replacing the IB, as set out in section 2.6 of CT-1
13. Investigational Medicinal Product Dossier (IMPD)/simplified IMPD, as set out in sections 2.7 and 2.7.3 of CT-1
14. GMP Compliance for the IMPs, as set out in section 2.7.1 of CT-1
15. Data related to the quality of the IMPs, as set out in section 2.7.2.2 of CT-1
16. NIMP dossier, as set out in section 2.8 of CT-1
17. The additional pieces of documentation, as set out in section 2.9 of CT-1
18. XML file of CTA form

*Please note that all of the aforementioned documents should be included in **only one CD-ROM**.*

[1] The fee for the application of an interventional clinical trial is:
a) 3000 euros plus 2,4%tax for a commercial clinical trial
b) 1500 euros plus 2,4%tax for a non-commercial clinical trial
Please make payable to: The Bank of Greece, account number 26303/8 EOF