

11. True/False about CEE

There are many 'myths' about Central and Eastern Europe (CEE). Some of them arose from superficial knowledge of this region, some of them simply from rumors. However, some of the opinions are true and here is the opportunity to verify them. Below are listed some statements overheard during different meetings with my opinion enclosed to each of them:

"Methods of medical treatment in CEE are different than in Western Europe"

False. As highlighted in Chapter 5, CEE physicians are very well educated and the recommended standards of treatment published by the local associations of medical professionals follow the most updated international guidelines.

"Clinical data from CEE are accepted by the US FDA"

True. There were many clinical trials conducted in CEE under US FDA IND and the collected data were used for the drug approval in the USA, and consequently in Europe. Moreover, the results of some key trials with substantial involvement of CEE countries were published in the most respected journals like "The Lancet" or "The New England Journal of Medicine" with obvious impact on the treatment standards worldwide.

"It is possible to conduct a study on borderline ethics in CEE"

False. Neither local investigators, nor IRB/IECs will accept any study on borderline ethics. I remember examples of studies that were approved in Western Europe, but rejected in CEE. Moreover, many large pharmas had adopted an internal guideline:

"Whatever you do in CEE you must do it at least twice as ethical as anywhere else". Any manipulation with ethical principles in this region has disastrous consequences for the study sponsor worldwide.

"There are many treatment-naive patients in CEE countries"

False. See Chapter 6.

"The patient accrual in CEE is very rapid and exceeds that in other countries"

True. However, it is important to be well prepared for it and to control this process. See chapter 7.

"Every single document in CEE must be translated into local language"

False. See Chapter 8.

"Sponsors conduct trials in CEE because it is much cheaper"

False. If one takes into consideration IRB/IEC, Regulatory Authorities or investigator/investigator's institution fee, the total is similar to the total in southwestern Europe, with the IRB/IEC fee sometimes exceeding it. Further reduction of costs depends on the reduction of the level of complexity and on quality management (see chapter 7).

"CEE is a beautiful part of Europe"

True. Those who visited Prague, Budapest, Cracow, Kiev and other CEE cities can confirm that research in CEE is not only attractive work, but also is quite pleasurable being in contact with the charm and beauty of European history.



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with the most updated local source.