Guidelines 07/2020 on the concepts of controller and processor in the GDPR
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Pages 21-22:

"*Example: Clinical Trials*
A health care provider (the investigator) and a university (the sponsor) decide to launch together a clinical trial with the same purpose. They collaborate together to the drafting of the study protocol (i.e. purpose, methodology/design of the study, data to be collected, subject exclusion/inclusion criteria, database reuse (where relevant) etc.). They may be considered as joint controllers, for this clinical trial as they jointly determine and agree on the same purpose and the essential means of the processing. The collection of personal data from the medical Adopted - version for public consultation record of the patient for the purpose of research is to be distinguished from the storage and use of the same data for the purpose of patient care, for which the health care provider remains the controller.
In the event that the investigator does not participate to the drafting of the protocol (he just accepts the protocol already elaborated by the sponsor), and the protocol is only designed by the sponsor, the investigator should be considered as a processor and the sponsor as the controller for this clinical trial".

<u>Comments</u>:

1) Could the example be applicable to pharmaceutical company (as sponsor)? If yes, could You please explicit that as per the following statement "*university or pharmaceutical company*"?

2) A "multicenter" clinical trial is conducted in several medical centers or clinics. Usually, not all investigators are involved in drafting the study protocol. If the protocol is drafted only by a few of them, what shall be the privacy role of the subjects who do not participate in the protocol drafting (joint-controllers or data processors)? Could You please specified it in the example?

[End of the document]