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Clinical trials

RECOMMENDATIONS regarding the conclusion of agreements in clinical trials

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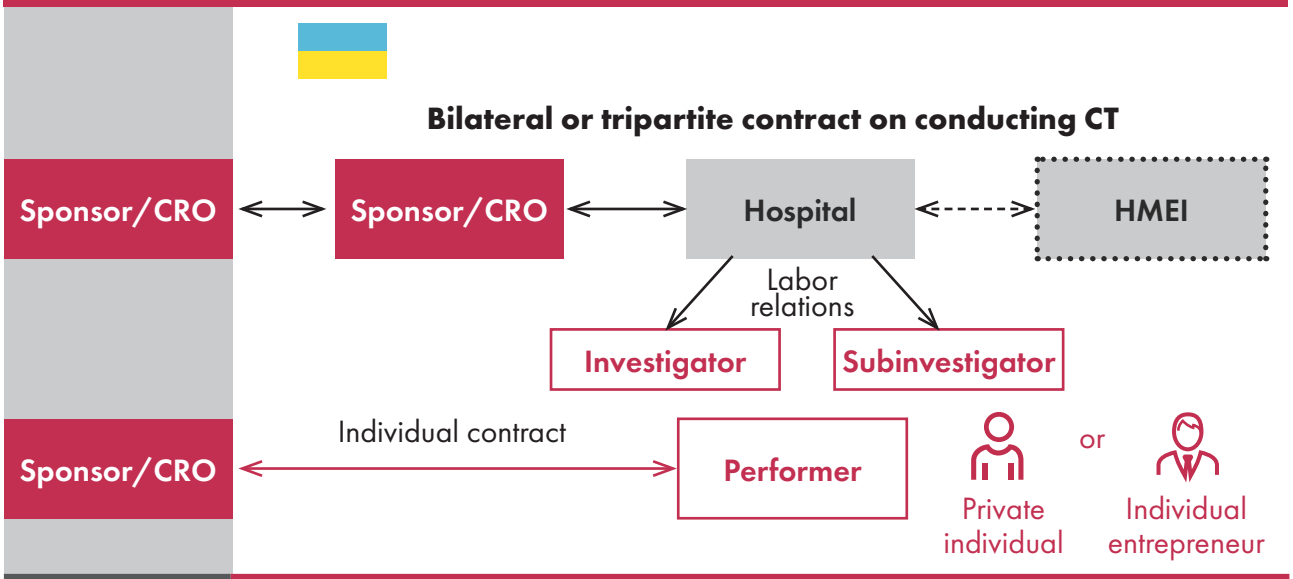
Due to the latest trends in the growth of tax and criminal risks in the field of clinical trials (CT), Arzinger law firm, as a permanent legal partner of the Clinical Trials Subcommittee of the European Business Association, provides these recommendations for concluding agreements in this area.

These recommendations are primarily intended to minimize risks associated with the conclusion of individual agreements between investigators and foreign sponsors / CROs, as this type of contractual relationship is currently under the closest attention of government authorities.

Standard contract model in CT



Type of contract:	**Agreement with Hospital or tripartite agreement with Hospital / Higher medical educational institution (HMEI)**
Title:	**"Agreement on conducting clinical trial ", "Clinical trial agreement" .**
Subject of agreement:	Under this agreement Hospital undertakes to conduct a clinical trial on conditions specified in the contract, and the Sponsor/CRO undertakes to pay Hospital (Hospital and HMEI) appropriate funds. Under a tripartite agreement Hospital provides necessary material and technical base (facilities and equipment) and part of the staff for conduction of a clinical trial, while HMEI provides participation of investigators in conduction of clinical trials.
Standard obligations under the contract:	**1.** Enrolment of study subjects; **2.** Obtaining written informed consent to participate in the trial; **3.** Maintaining and storage of all source medical documents, storage of other documents related to the trial; **4.** Facilitating activities of the ethics committee and study group, etc.
Comments:	Conduction of a clinical trial, as well as other obligations under this agreement, is in fact carried out by the investigators who act **exclusively** as employees of Hospital /HMEI. Thus, services are provided by investigators (and other staff) who are employed by Hospital / HMEI.
Type of contract:	**Individual contract with the Performer (Investigator)**
Title:	**"Service Agreement", "Consulting Services agreement", "Agreement".**
Subject of agreement:	Under this agreement, the Performer undertakes to provide consulting services, data processing services and other services related to the conduction of clinical trials.

Standard obligations under the contract:	**1.** Providing consulting services on protocol design; **2.** Ensuring compliance with the sponsor's requirements and accuracy of information when filling out CRFs; **3.** Providing consulting services on the safety and efficacy of the method of treatment applied according to the protocol, and process the appropriate report documentation in accordance with the requirements of the sponsor; **4.** Compiling reports in the form and content specified by the sponsor; **5.** Carrying out regular evaluation of trials conditions and determining potential number of study subjects, etc.
Comments:	In order to avoid confusion with other agreements concluded with Hospital and HMEI, such individual agreements should not be called "Agreement on conducting a clinical trial"," Clinical trial agreement ", etc. It is also recommended to call the parties "Performer" (instead of "Investigator") and "Client".
Type of contract:	**Individual agreement with the Performer (Subinvestigator)**
Title:	**"Service Agreement", "Consulting Services agreement", "Agreement".**
Subject of agreement:	Under this agreement, the Performer undertakes to provide consulting services, data processing services and other services related to the conduction of clinical trial.
Standard obligations under the contract:	**Option 1.** The contract with the Subinvestigator includes part of the responsibilities of the Principal Investigator (in that case they should be excluded from the contract with Principal investigator); **Option 2.** The contract with the Subinvestigator specifies the same responsibilities as in the contract with Principal investigator, but with indication that the Subinvestigator supports and assists the Principal investigator in performing such responsibilities together with other members of the study group. **Option 3.** The Subinvestigator concludes a contract not with the Sponsor or CRO, but with the Principal investigator, in which the latter delegates part of his/her responsibilities to the Subinvestigator. The possibility of such delegation should be stipulated in the contract with Sponsor / CRO.
Comments:	In order to avoid confusion with other agreements concluded with Hospital and HMEI, such individual agreements should not be called "Agreement on conducting a clinical trial"," Clinical trial agreement ", etc. It is also recommended to call the parties "Performer" (instead of "Subinvestigator") and "Client".

Type of contract:	**Agreement on cooperation between Hospital and HMEI (concluded in case of signing a tripartite agreement between the Sponsor / CRO, Hospital and HMEI)**
Title:	**"Cooperation Agreement"**
Subject of agreement:	Cooperation between Hospital and HMEI in the framework of conducting clinical trials.
Standard obligations under the contract:	Within the framework of this agreement, the parties will regulate the use of the material and technical base of the Hospital, the involvement of HMEI employees in conducting clinical trials and other issues.

Recommendations on conclusion of contracts

1. Under an individual contract, the Performer **must provide** services related to performance of intellectual work (analytical, informational, expert-advisory, making reports on clinical trials, etc.), which are usually related to the provision of consulting services and data processing services.

Under this agreement, the Performer **may not provide** clinical trial services or any other services related to his functions as an employee of a Hospital or HMEI. Therefore, in the individual contract it is necessary to very carefully stipulate the subject and responsibilities of the Performer so that they do not duplicate with the subject and services provided to the Sponsor / CRO by the Hospital (or HMEI) under separate agreements.

As an additional tool to avoid misinterpretation of certain services in the individual contract, **it is recommended to add a reservation of the following content:** *"Under this agreement The Performer undertakes to provide only consulting, data entry and processing services in accordance with the terms of the Agreement. Any other provisions of this Agreement that define the duties and functions of the Performer shall be interpreted by the parties as those generating certain data and information to be processed by the Performer in accordance with requirements of the Agreement and in respect of which the Performer will provide consulting and data processing services".*

2. **Potentially, the investigator can provide services for the creation of intellectual property objects.** However, in this case, a number of requirements must be met, in particular the agreement must contain provisions on the creation by the investigator of an intellectual property object, the procedure of registration and identification of the created object, the procedure for transferring such object to the Sponsor / CRO, as well as requirements for transferring exclusive intellectual property rights on object: list of rights transferred, remuneration of Performer for the transfer of rights, the period during which the rights are transferred, the territory of the transfer, etc. The contract must contain all the conditions defined by current legislation which are essential for the contract and the transfer of exclusive intellectual property rights. The moment of creation of the object must be clearly defined, as well as conclusion of separate acts of transfer of rights to the objects from the Performer to the Sponsor / CRO must be done.

If stipulated requirements for such services are not met, it is **not recommended** to include them into the agreement.

If the Performer performs such work as an individual entrepreneur being a payer of a single tax, the contract price must be clearly divided to the cost of work on the creation of intellectual property object and the Performer's remuneration for the transfer of intellectual property rights, as these transactions may be subject to different tax regimes.

3. In the individual contract with the Performer **it is necessary to avoid provisions that The Performer conducts clinical trials and / or provides services related to medical practice** (any manipulations of a medical nature, namely activities aimed at prevention, diagnosis, treatment and rehabilitation in connection with diseases, injuries, poisonings and pathological conditions, should not be the subject of an individual contract with the Performer).

It is also additionally **recommended to include a separate reservation** stating that the Performer does not provide any medical services. **For example:** *"The activity of the Performer does not include the performance of any actions that require a special permit (license). Actions on carrying out any examinations, analyzes, diagnostics, on appointment and change of medical and / or non-medical treatment, carrying out other procedures on providing medical assistance in the Study process is performed by the competent staff of the Hospital in accordance with their official duties".*

4. In the individual contract with the Performer it is necessary to provide correlation of the description of services (works, duties) of the Performer, specified in budget annexes and acts to the contract with the Performer, with the corresponding services (works, duties) provided by the text of such an individual contract. While drfting the provisions of the relevant annexes and acts, it is necessary to follow the same recommendations as above for individual contracts, namely: to avoid the provisions that the Performer under a separate contract conducts clinical trial, or provides services related to medical practice (CT, MRI, conducting various tests and other medical manipulations, etc.) and avoid duplication of functions with the Hospital and HMEI.

However, in practice, payment under individual contracts is usually connected with the amount of visits of study subjects and, in some cases, with additional medical actions. If this cannot be avoided, then to minimize the relevant risks, we recommend:

- Making before the schedule indicating the visits and the corresponding payments a reservation which explains that the scope of consulting and data processing services depends on a number of patient visits

- Make before the schedule with a list of additional manipulations (including manipulations of medical nature, if they cannot be excluded) a similar reservation that explains that payment is not made for the medical services listed in the schedule (CT, MRI etc.), but for consulting and data processing services to be provided based on the information obtained during the actions listed in the schedule.

- If in the budget annex there is only one schedule with both visits and additional services of medical nature – both reservations can be combined. The same reservations should be included in the acts.

5. It is necessary to make sure that related agreements (agreements with Hospital or Hospital/HMEI, agreements with other performers (Subinvestigators), agreements on cooperation of HMEI and Hospital) also contain the provision that the investigator / subinvestigator under a separate contract provides only consulting services and data processing services. You should also ensure that services and obligations of investigators / Subinvestigators as performers under individual contracts do not repeat their work duties as employees of the respective Hospitals and HMEI.

6. The contract with Hospital or Hospital / HMEI must contain provisions that:

- Investigators / Subinvestigators are allowed to use clinical trial materials and data and also the material and technical base of Hospital / HMEI during non-working hours for the provision of services under their individual contracts;
- The Sponsor / CRO reimburses the Hospital / HMEI for usage by the Investigator / Subinvestigator of the material and technical base of the Hospital / HMEI during the provision of services under an individual contract.

7. It is recommended both in the contract with the Hospital (Hospital and HMEI) and in the individual contract with the Performer to determine a **detailed algorithm of actions in case of an insured event**, as well as obligation of the parties to prepare and provide documents necessary for the registration of the relevant insured event.

8. The Investigator / Subinvestigator as the Performer under an individual contract is an independent party to the relevant contract and to the negotiation process with the client (Sponsor / CRO) and has the opportunity to explain his/her position in negotiations concerning the text of the agreement and additional documents in respect of risks arising from templates provided by such client. If as a result of such negotiations it was not possible to change the relevant template provisions that pose risks to the Performer, **it is recommended to add to the contract or draw up a separate the document on the dissemination of expense and losses** that may occur due to the presence of «risky» (defective) contract provisions.

Recommendations on taxation

9. The Performer may not provide services under individual contracts on a regular basis, if he is not registered as an individual entrepreneur. **Regular provision of services without registration can cause serious financial, tax and criminal risks.**

10. Services that constitute the subject of an individual contract must comply with the registered KVED (Ukrainian Industry Classification System) codes of the Performer, which are specified in the Unified State Register of Legal Entities, Individual entrepreneurs and public formations and the Register of single tax payers. **It is recommended, in particular, to have the following codes: 74.90, 63.99, 63.11.**

11. For the purposes of providing services under an individual agreement with the Sponsor / CRO, the Performer, who is registered as an individual entrepreneur, can be either on the general taxation system or on the simplified while being **the payer of the single tax only of the 3rd group** (annual income limit – UAH 7 million). Other individual entrepreneurs with whom Performer concludes contracts can be payers of the single tax of the 3rd and 2nd group. At the same time, if they are taxpayers of the 2nd group, they can enter into agreements only with single tax payers and cannot provide services to taxpayers who are on the general taxation system.

12. The Performer under the individual contract which is on the simplified system of the taxation (the single tax of the 3rd group) **may voluntary register as the VAT payer**, – There is no obligation for single tax payers to register as VAT payers. If registered as a VAT payer, the single tax rate for an individual entrepreneur who is a single tax payer of group 3 is reduced from 5% to 3% of income.

13. Performer which is on the general taxation system is obliged to register as a VAT payer in case of receiving a payment for providing services **during the last 12 months in the amount of over 1 million UAH.** Such limits do not apply to taxpayers on the simplified taxation system.

14. If the Performer is registered as a VAT payer, the necessity to charge and pay VAT depends on the place of supply of services. If the place of supply of services is Ukraine (for example, both the Client and the Performer are residents of Ukraine), the Performer has an obligation to charge and pay VAT. If the place of delivery of services is located outside of Ukraine and the parties have correctly drafted the contract, **the obligation to charge and pay VAT does not arise.** The place of supply of services is determined taking into account provisions of Art. 186.2 – 186.4 of Tax Code of Ukraine.

15. As for the agreements between the Sponsor / CRO and the Hospital, the VAT requirements are similar – the Hospital is obliged to register as a VAT payer in case of receiving payment for services provided during the last 12 months in the amount of over UAH 1 million. In this case, the obligation to charge and pay VAT depends on the nature and place of supply of a particular service provided by the Hospital.

16. In case of receiving the act of tax audit and the decision on additional tax accruals (the TND) based on the results of the tax audit, we recommend using available means of both pre-trial and judicial appeal. It worth noting that the complaint against the TND must be filed to the State Tax Service of Ukraine within 10 working days following the date of receiving the challenged TND. It is also recommended to file the claim with the court within 10 working days following the date of receiving the TND or the negative decision based on the results of consideration of the complaint against the TND. **It should be noted, that challenging the TND outside the 10-day period constitute the basis for the taxpayer to incur tax debt.**