Clinical Trials of New Medicines in Practice: Contracts, Budgets, and Negotiation

<style> .cuni-clean-wrapper { font-family: inherit; color: inherit; font-size: inherit; line-height: 1.55; width: 100%; max-width: 100%; margin: 0; padding: 0; box-sizing: border-box; } .cuni-clean-wrapper *, .cuni-clean-wrapper *::before, .cuni-clean-wrapper *::after { box-sizing: border-box; } /* SUMMARY */ .cuni-annotation-hero { margin: 0 0 18px 0; padding: 12px 14px; background: #fff7f7; border-left: 3px solid #d32f3f; border-radius: 0 4px 4px 0; font-size: inherit; line-height: 1.55; font-weight: 400; } .cuni-annotation-hero .title-label { display: block; margin: 0 0 6px 0; color: #d32f3f; font-size: 0.95em; font-weight: 700; text-transform: uppercase; } /* CTA */ .cuni-cta { margin: 0 0 22px 0; padding: 0; font-size: inherit; line-height: 1.5; } .cuni-cta-text { margin: 0 0 9px 0; color: #444; font-weight: 400; } .cuni-btn-link { display: inline-block; margin: 0; padding: 8px 15px; background: #d32f3f; color: #fff !important; border-radius: 3px; text-decoration: none !important; font-size: inherit; font-weight: 400; } .cuni-btn-link:hover { background: #b71c1c; } .cuni-btn-secondary { display: inline-block; margin: 0 0 0 8px; padding: 7px 14px; color: #d32f3f !important; border: 1px solid #d32f3f; border-radius: 3px; text-decoration: none !important; font-size: inherit; font-weight: 400; } .cuni-btn-secondary:hover { background: #fff7f7; } /* HEADINGS */ .cuni-heading { margin: 24px 0 10px 0; padding: 0 0 5px 0; color: #d32f3f; font-family: inherit; font-size: 1.05em; line-height: 1.3; font-weight: 700; border-bottom: 1px solid #dfe3e6; } .cuni-heading:first-of-type { margin-top: 0; } /* BASIC INFORMATION */ .cuni-params-inline { margin: 0 0 20px 0; padding: 0; list-style: none; } .cuni-params-inline li { margin: 0 0 5px 0; padding: 0; font-size: inherit; line-height: 1.5; font-weight: 400; } .cuni-params-inline strong { color: #d32f3f; font-weight: 400; } /* PARAGRAPHS */ .cuni-clean-wrapper p { margin: 0 0 14px 0; padding: 0; font-size: inherit !important; line-height: 1.55; font-weight: 400; } /* LEARNING OUTCOMES */ .cuni-outcomes-list { margin: 0 0 20px 0; padding-left: 18px; } .cuni-outcomes-list li { margin: 0 0 6px 0; padding-left: 2px; font-size: inherit; line-height: 1.5; font-weight: 400; } /* CONTACTS */ .cuni-person-wrapper { margin: 0; padding: 0; } .cuni-contact-group { margin: 0 0 16px 0; padding: 0; } .cuni-contact-group:last-child { margin-bottom: 0; } .cuni-contact-group h4 { margin: 0 0 2px 0; padding: 0; color: #444; font-family: inherit; font-size: 0.9em; line-height: 1.4; font-weight: 400; text-transform: uppercase; } .cuni-contact-group p { margin: 0 0 2px 0 !important; padding: 0; font-size: inherit !important; line-height: 1.45; font-weight: 400; color: inherit; } .cuni-contact-group a { color: #d32f3f; font-size: inherit; text-decoration: none; font-weight: 400; } .cuni-contact-group a:hover { text-decoration: underline; } @media (max-width: 600px) { .cuni-btn-secondary { margin: 8px 0 0 0; } } </style>

 <!-- SUMMARY --> Summary This lecture offers academic staff a practical perspective on the contractual and financial aspects of clinical trials and explains how to negotiate effectively with CROs and Sponsors. It shows how well-structured contracts and budgets protect the institution, the Principal Investigator, and the study team, while potentially bringing more than 25% in additional funding to the research site. <!-- CTA -->   Interested in the program? Please submit your request using the form. We will then contact you to discuss the details and arrange a suitable date. Request Form   Contact the Lecturer <!-- BASIC INFORMATION --> <h2 class="cuni-heading">Basic Information</h2> <ul class="cuni-params-inline"> Program type: Lecture   Target audience: Academic and research staff, physicians, Principal Investigators (PIs), and other professionals involved in clinical research   Duration: 2–3 teaching hours, as needed   Capacity: Unlimited   Language: Czech   Date: By arrangement   <!-- DETAILED DESCRIPTION --> <h2 class="cuni-heading">Detailed Description</h2> The lecture focuses on the contractual and financial aspects of clinical trials from the perspective of an academic or hospital institution. Participants will become familiar with the main types of contracts and documents, including CDA, Clinical Trial Agreement (CTA), Master Agreement, Data Processing Agreement (DPA), Budget Agreement, ancillary agreements, and amendments.   Particular attention will be paid to key CTA provisions, especially liability and indemnification, payment terms, publications, intellectual property, data protection, and contract termination. A dedicated section will demonstrate how to negotiate effectively with CROs and Sponsors, how internal limits, fallback positions, and escalation procedures work, and will offer a “view from the other side of the table” based on practical contract management experience with leading global CROs.   TCPP, Fair Market Value, ABAC, start-up and administrative fees, and budget escalation will also be discussed. Practical examples will demonstrate how to strengthen the legal and financial position of the research

site. The session will include discussion and an opportunity for questions. <!-- LEARNING OUTCOMES --> <h2 class="cuni-heading">What Participants Will Learn</h2> <ul class="cuni-outcomes-list"> An overview of the main types of contracts and documents used in clinical trials   An understanding of the key provisions of the Clinical Trial Agreement (CTA)   Practical skills for negotiating with CROs and Sponsors   An understanding of internal limits, fallback positions, and escalation procedures   An understanding of the financial aspects of clinical trials, including TCPP, Fair Market Value, ABAC, start-up, and administrative fees   The ability to strengthen the legal and financial position of an academic or hospital institution   <!-- CONTACTS --> <h2 class="cuni-heading">Contacts</h2>   <h4>Program Lead</h4> Mgr. BcA. Ivo Svejkovský Ph.D., MBA   Director of the Centre for Knowledge and Technology Transfer at Charles University ivo.svejkovsky@ruk.cuni.cz | +420 771 128 396   <h4>Lecturer</h4> Mgr. BcA. Ivo Svejkovský Ph.D., MBA   <h4>Contact Person</h4> Mgr. BcA. Ivo Svejkovský Ph.D., MBA ivo.svejkovsky@ruk.cuni.cz | +420 771 128 396