Clinical Trials of New Drugs 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; } /* ANNOTATION */ .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; } /* 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>

 <!-- ANNOTATION --> Annotation The lecture will provide practical insight into the system of clinical trials of new medicinal products and Sponsor–CRO–site collaboration. Students will understand the importance of effectively negotiating a Clinical Trial Agreement (CTA) and budget to protect the hospital, principal investigator and study team, and learn why active negotiation can bring the site more than 25% in additional funding. The lecture will also briefly introduce the regulatory framework and the roles of EMA, FDA and SÚKL. <!-- CTA -->   Interested in the programme? Please submit your request via the form. Based on your request, we will arrange the details and agree on a suitable date. Arrange a date   Contact the lecturer <!-- BASIC INFORMATION --> <h2 class="cuni-heading">Basic Information</h2> <ul class="cuni-params-inline"> Programme type: Lecture with time for discussion or a practical workshop   Primary target group: Bachelor's and Master's students and PhD students   Also available for: Academic staff, if required   Duration: 2–3 teaching hours, as required   Capacity: No limit   Language: Czech, English   Date: By arrangement   <!-- DETAILED DESCRIPTION --> <h2 class="cuni-heading">Detailed Description</h2> The lecture will introduce the practical operation of clinical trials of new medicinal products, covering the roles of the pharmaceutical company (Sponsor), Contract Research Organisation (CRO) and research site, the phases of clinical research and work with the study protocol, as well as the contractual, financial and regulatory aspects of conducting a clinical trial.   Particular emphasis will be placed on the Clinical Trial Agreement (CTA), its key provisions, payment terms, liability, data protection and the negotiation process between the CRO, sponsor and hospital. Students will also learn about the preparation and negotiation of clinical trial budgets, the principles of TCPP, Fair Market Value and Anti-Bribery and Anti-Corruption, as well as mechanisms for escalating budget requests to the sponsor.   Practical examples will demonstrate

how effective contractual and budget negotiations can protect the hospital, principal investigator and study team and can significantly increase the funding available for conducting a clinical trial. The regulatory framework for clinical trials and the roles of EMA, FDA and SÚKL will also be briefly introduced. The lecture will include time for discussion and answering students' questions. <!-- LEARNING OUTCOMES --> <h2 class="cuni-heading">What Participants Will Learn</h2> <ul class="cuni-outcomes-list"> How clinical trials work in practice   Who the Sponsor, CRO and site are and how they cooperate   What to look out for in a Clinical Trial Agreement (CTA)   How a clinical trial budget is prepared and negotiated   What can actually be influenced when negotiating with the sponsor   How to protect the interests of the hospital, principal investigator and study team   What roles EMA, FDA and SÚKL play   Practical examples of contractual and budget negotiations   <!-- CONTACTS --> <h2 class="cuni-heading">Contacts</h2>   <h4>Programme Coordinator</h4> Mgr. BcA. Ivo Svejkovský Ph.D., MBA ivo.svejkovsky@ruk.cuni.cz | +420 771 128 396   <h4>Lecturer</h4> Mgr. BcA. Ivo Svejkovský Ph.D., MBA   Director of the Centre for Knowledge and Technology Transfer at Charles University   <h4>Contact Person</h4> Mgr. BcA. Ivo Svejkovský Ph.D., MBA ivo.svejkovsky@ruk.cuni.cz | +420 771 128 396