Up-to-date information for applicants (e.g. sponsors, contact persons, CRO) submitting applications for approval of a clinical trial on products of the following nature: gene therapy medicinal products, somatic cell therapy medicinal products (including cells of xenogeneic origin) or medicinal products containing genetically modified organisms.

Following our existing experience with reviews of applications for approval of clinical trials on the above mentioned investigational medicinal products and the compexity thereof, the applicants are kindly requested to inform the Institute of the planned submissions in advance (by e-mail: alice.nemcova@sukl.cz). This information should detail the nature of the medicinal product and the anticipated date of submission. The applicant is also requested to highlight the nature of the medicinal product in the covering letter and ensure that pertinent parts of the application form are filled in properly.
Please note that the medicinal products of the nature mentioned above are reviewed within a 90-day period, which can be, when appropriately justified, extended by additional 90 days. No timelines are set for the review of medicinal products of xenogeneic origin.
Although there are no legal grounds for this guidance, we would highly appreciate if this approach could be put into practice, helping us organise our work more effectively. Thank you for you co-operation.