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Feasibility assessment foroncology trials

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The growing complexity of trials connected with the success of personalized medicine and advances inimmuno-oncology requires a diverse range of expertise at the stage of feasibility assessment. Currently most of oncology clinical trials fail to enroll patients on time and this requires the study sponsor additional time, efforts and money. The main reason of that delays is improper evaluation of operational doability of the trials and especially in International environment. Keeping up to datewith the trend of drug development in oncology, we have implemented an algorithm for translating clinical, laboratory, imaging and other protocol requirements into effective site interviews, the development of effective study geomix, and plausible enrollment estimates.

The feasibility assessment algorithm includes several steps:

- Analysis of medical elements of the study protocol: This includes the comparison of study treatment and diagnostic proceduresversuscurrent International standards and identification of key entry criteria determining the target patient population.
- Evaluation of regulatory and ethical aspects: Modern trials frequently apply gene-modified therapy, including ex-vivo processed stem cells. This approach can trigger multiple issues with regulatory and ethics bodies in various countries. Early-phase trials, pediatric studies and studies testing radioactive materials and controlled substances represent another potential concern for regulatory authorities.
- Availability of laboratory tests and study-related logistic constraints: Extended laboratory panels, including tests on live cells, may apply logistic restrictions, which should be taken into consideration while planning the location of sites. Capabilities of local laboratories represent another matter for professional review, since it may affect the quality of the study data and safety of study subjects.
- Profiling of study sites: Analysis of the treatment and diagnostic requirements allow scompiling detailed profile of a potential study site. This provides ground for thorough estimate of availability of sites in each particular country and identification of the most challenging protocol requirements.
- Development of the feasibility questionnaire: Having identified the patient population, limiting factors and sites requirements, we formulate them as questions in brief feasibility questionnaires, placing them in a general-to-specific pattern.
- Availability of study sites (based on the collected questionnaires) and their access to study population: After such a feasibility assessment,study sponsor receives a report containing plausible patient enrollment scenarios, the analysis of the study protocol challenges along with proposals for their solution, as well as the preliminary budget of the whole project, put together based on the optimal study scenario.

Biography

Maxim Belotserkovskiy, MD (1987), PhD (1992), Associate Professor of Pathological Physiology (2000), Head of Medical Affairs Division of PSI CRO AG, published more than 140 papers and abstracts.

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