Presidential symposium 3: Presidential symposium / Special session to celebrate reaching one thousand JSMO-certified medical oncologists “Career development of the JSMO-certified medical oncologists – learning from the USA.”

How to become a clinical trialist

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In order to focus on clinical trials, you will need to learn how to read and write protocols from start to finish. Writing a protocol begins with the LOI, “letter of intent”.

You need to be familiar with the format; background, rationale, study design, and practical aspects. Other important components include understanding of the budget and regulatory process. Attending protocol review committee as both a presenter and also a reviewer will help to familiarize you with these processes. You need to be prepared to answer reviewer comments including how the outcome of the trial impacts unmet needs, and be able to explain limitations of the study. Basic statistical knowledge will be established through dialog between you and statisticians. You will also learn how to present your protocol in an energetic and convincing way in front of committee. Once protocols are approved, you will then learn how to execute trials in conjunction with your own institutional clinical trial office members including regulatory, research coordinators, and investigational pharmacy staff. Interactions with the trial sponsors’ medical and research monitors will require you to relay important facts in a timely fashion. To be able to accrue patients to clinical trials, your patient volume will be important because not all patients are eligible for trials. Another key aspect of successful accrual is to maintain close communication with referral centers and doctors, as well as reaching out to community physicians to introduce yourself and provide information about what trials are available. In the United States, clinical trial options are considered to be opportunities rather than experiments. Of course through consenting process, you need to maintain neutrality regarding the patient’s decision making. To successfully complete clinical trials and maintain compliance it is crucial that you remain accessible to staff and patients throughout this process.