

Experience sharing: how do we initiate and conduct large scale IIT

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Oncology investigator initiated trials are important in that it can provide answers to scientific questions important to patients, but not often addressed by sponsor initiated trials, such as expansion of existing indication, developing novel combinations of already approved agents, developing novel therapeutics especially for rare cancers, finding optimal sequence and duration of already approved treatments in the post-marketing setting, and also in building valuable real-world evidence. However, conducting high quality investigator-initiated trials require strong investigator groups, funds, resources, and clinical trial infrastructures. In most of the high-income countries, such as US, Europe, and Japan, clinical trial cooperative groups are funded by national funds, while most middle-and low-income countries lack such governmental support, bringing the biggest hurdle to high-quality investigator-initiated trials.

Korean Cancer Study Group was founded in 1998, to perform high quality investigator initiated clinical trials in Oncology. From 2012 to 2017, KCSG received a grant from National R&D Program for Cancer Control, Ministry of Health & Welfare, Republic of Korea to build a multicenter cooperative group clinical trial infrastructure. With the National Cancer Control grant, KCSG was able to establish datacenter, build SOPs and infrastructure necessary to perform high quality multicenter & multinational clinical trials. KCSG has conducted more than 200 clinical trials, published more than 100 journal articles, and more than 36,000 patients have been enrolled in KCSG clinical trials.

KCSG have protocol review committee, data center for clinical operations, independent QA department, and 10 disease committee including breast cancer committee, where study concept from principle investigators are discussed and refined to full protocol. Data center supports whole clinical trial operations; from IRB submission, budget and contract negotiation, data management, site management, study conduct, regulatory affairs, monitoring, and audit.

Korean Breast Cancer Study Group was established in 2008, from clinical trial committee of Korean Breast Cancer Society, and is performing many multidisciplinary breast cancer clinical trials. Both KCSG and KBCSG has conducted large scale IITs of important scientific value. In the meeting, experience of KCSG and KBCSG in building clinical trial infrastructure and conducting large scale IITs will be shared, and examples of successful large scale IITs will be presented.