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East Asian Gynecologic Oncology Trial Group (EAGOT): founding history and future perspective

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ABSTRACT

Racial and regional differences exist in morbidity, histology, drug response, toxicity, and prognosis of gynecologic cancer. However, most large-scale phase III studies have been conducted in Western countries, and these data on Asians, who account for more than half of the world's population, are limited. To build a global clinical trial network in Asia, four clinical trial groups with high expertise and international competitiveness in East Asia, namely the Japanese Gynecologic Oncology Group in Japan, the Korean Gynecologic Oncology Group in Korea, the Taiwanese Gynecologic Oncology Group in Taiwan, and the Chinese Gynecologic Cancer Society in the People's Republic of China, established a new group called the East Asia Gynecologic Oncology Trial Group (EAGOT) on November 19, 2021. It includes four committees: the Cervical Cancer Committee, Uterine Corpus Cancer Committee, Ovarian Cancer Committee, and Translational Research Committee. The purpose of EAGOT is to conduct international clinical trials in an effort to provide the best treatments for Asian women affected by gynecologic cancer. Discussions on new collaborative clinical trials have already begun. The first Annual EAGOT Meeting was held on May 25-27, 2023 in Niigata, Japan. EAGOT, the largest healthcare/investigational innovation network in Asia in the area of gynecologic cancers, will become a platform for establishing standards of care and lead to guidelines for Asian women suffering from gynecologic cancer. The harmonization of regulatory/investigator-initiated clinical trials, simultaneous approval of unapproved drugs in the four countries under a common protocol, and expansion of indications will improve the prognosis of gynecologic cancers in Asia in the near future.

Keywords: Clinical Trial Group; JGOG; KGOG; TGOG; CGCS; EAGOT

Synopsis

In an effort to provide the best treatments for Asian women affected by gynecologic cancer, four clinical trial groups with high expertise and international competitiveness in East Asia, Japanese Gynecologic Oncology Group in Japan, Korean Gynecologic Oncology Group in Korea, Taiwanese Gynecologic Oncology Group in Taiwan, and Chinese Gynecologic Cancer Society in the People's Republic of China, established a new group called the East Asia Gynecologic Oncology Trial Group.



Conflict of Interest

No potential conflict of interest relevant to this article was reported.

Author Contributions

Conceptualization: E.T., O.A., K.J., L.C., W.X., K.Y.M.; Methodology: E.T., O.A., K.J., L.C., W.X., K.Y.M.; Project administration: E.T., O.A., K.J., L.C., W.X., K.Y.M.; Writing - original draft: E.T.; Writing - review & editing: E.T., O.A., K.J., L.C., W.X., K.Y.M.

INTRODUCTION

Recent technological innovations in genomic analysis and drug development have led to the rapid expansion of precision medicine for gynecologic cancers. In gynecologic cancers, racial and regional differences are well known to exist in morbidity, histology, drug response and toxicity, and prognosis. For example, clear cell carcinoma accounts for approximately 25% of primary ovarian carcinomas in Japan, Korea, Taiwan, and China, but only 4% in the United States. The frequency of germline *BRCA* pathogenic variants in high-grade serous ovarian carcinoma has been reported to be 28.5% in Japan, 26.2% in Korea and 27.2% in China, but only 16.0% in the United States [1-4].

Pharmacoethnicity, or ethnic diversity in drug response or toxicity, results from the combined interaction of many factors, principally environmental differences in the environment, local practice habits, regulatory control, drug–drug interaction, and genetic differences [5]. A study on ethnic differences in toxicity in early phase clinical trials for oncology drugs established that the maximum tolerated dose (MTD) of Temsirolimus, Topotecan, and Fludarabine was higher in Western countries than in Japan. In contrast, MTD of Capecitabine is much higher in Japan. These findings suggest that the results of clinical trials are strongly affected by ethnic differences [6].

Although pharmacoethnicity may influence the results of the clinical trial, most large-scale phase III studies have been conducted mainly in Western countries, and data on Asians, who account for more than half of the world's population, are limited. For example, a SOLO1 study examining the benefit of Olaparib as maintenance therapy for newly diagnosed ovarian cancer found that only 47 of 391 (12.1%) randomized patients were from Asia [7]. Similarly, in a SOLO2 study on the benefit for platinum-sensitive relapsed ovarian cancer, only 13 of 295 (4.4%) randomized patients were from Asia. Therefore, it is important for Asian countries to cooperate and establish a network of clinical trial groups in Asia [8].

To realize a global clinical trial network in Asia, four clinical trial groups with high expertise and international competitiveness in East Asia, namely the Japanese Gynecologic Oncology Group (JGOG) in Japan, the Korean Gynecologic Oncology Group (KGOG) in Korea, the Taiwanese Gynecologic Oncology Group (TGOG) in Taiwan, and the Chinese Gynecologic Cancer Society (CGCS) in the Republic of China, established a new group called the East Asia Gynecologic Oncology Trial Group (EAGOT) on November 19, 2021. We introduce the activities of JGOG, KGOG, TGOG, and CGCS, and the founding history of EAGOT.

ACTIVITIES OF JGOG, JAPAN

JGOG is the largest gynecologic cancer research group in Japan, in which all core clinical research hospitals in Japan participate. JGOG has a history of more than 40 years since the establishment of its predecessor, the Cervical Cancer Chemotherapy Research Group in 1981. As of May 2023, JGOG has 178 registered facilities with 1017 regular members. To promote multi-center research projects, JGOG-accredited facilities include those with reliability assurance, such as the establishment of institutional review board/ethics committees and quality control of trials.



JGOG is one of the founding members of the Japanese Cancer Trial Network (JCTN), which was organized in 2014 as a voluntary consortium of major cancer cooperative groups in Japan. JCTN has issued three common guidelines to standardize procedures for adverse event reporting, central monitoring, and site visit audits in clinical trials which are compliant with International Conference on Harmonization-Good Clinical Practice (ICH-GCP) and the Japanese Ethical Guideline of Medical Research for Human Subjects and the Clinical Trials Act. The clinical research project of JGOG includes 9 committees: Cervical Cancer Committee, Uterine Cancer Committee, Ovarian Cancer Committee, Translational Research Committee, Data Management Committee, Radiation Therapy Committee, Supportive and Palliative Medicine Committee, Pathology Committee, and Institutional Accreditation and Audit Committee. These committees are involved in the planning and implementation of clinical research, which forms the backbone of IGOG. In addition to clinical trials, IGOG also engages in international collaboration, liaison, and education of young fellows interested in clinical research in gynecologic cancer. The JGOG has conducted and announced many Phase III and II trials and has participated in international physician-initiated trials of clinical groups, such as the Gynecologic Cancer Intergroup (GCIG) mainly in Europe and NRG-Oncology in the US [9-13].

ACTIVITIES OF KGOG, KOREA

KGOG is a prominent research organization dedicated to gynecologic cancer in South Korea. Established in 2002 as a subsidiary of the Korean Society of Gynecologic Oncology & Colposcopy, KGOG focuses on conducting clinical trials. With 73 registered institutions and 168 regular members, including gynecologic oncologists, pathologists, radiation and medical oncologists, and statistician KGOG is recognized as a government-approved corporation. Its primary objective is to enhance public health by facilitating domestic and international multicenter clinical trials on various aspects of gynecologic cancer treatment, including diagnosis, surgery, chemotherapy, and radiation therapy. Moreover, KGOG is taking a crucial role in training and educating experts in gynecologic cancer clinical trials.

The organization operates through several committees, each addressing specific areas of gynecologic cancer research, such as Cervical Cancer, Uterine Corpus-Gestational Trophoblastic Tumors, Ovary-Fallopian Tube, Surgery, Radiotherapy, Chemotherapy, Translational Research, Developmental Diagnostic and Therapy, Symptom Benefit, Cancer Prevention & Control, Pathology, Publication, Audit, International Relations, Statistics and Data, and Data Safety Monitoring Board. These committees have significantly contributed to the advancing of gynecologic cancer research in South Korea by leading and participating in studies conducted by KGOG.

KGOG has actively sought collaborations with international organizations such as the GCIG and NRG-Foundation (NRG-F). These collaborative efforts have significantly strengthened KGOG's research capabilities, resulting in remarkable clinical outcomes [14-18]. Currently, KGOG is engaged in 35 ongoing clinical trials, including studies conducted in partnership with GCIC, NRG, and GOG.



ACTIVITIES OF CGCS, PEOPLE'S REPUBLIC OF CHINA

The China Anti-Cancer Association (CACA) was established on April 28th, 1984, while the Cervical Cancer Committee was established in 1986. Later in 1994, Gynecologic Cancer Committee was used to replace the Cervical Cancer Committee and in 2016, CGCS was formally named as an official committee for national Gynecologic Cancer Society in China. Under the leadership of past chairmen, CGCS has gradually developed into an oncologic research organization with national and even international influence. As of April 2023, CGCS has 157 registered committee members and 5,862 regular members. At present, CGCS is subdivided into 3 committees: Cervical Cancer Committee, Uterine Cancer Committee, and Ovarian Cancer Committee.

CGCS is committed to achieving standardized diagnosis and treatment of gynecologic tumors in Chinese mainland. CGCS has issued 7 Gynecological Cancer Guidelines including cervical cancer, ovarian cancer, endometrial cancer, uterine sarcoma, malignant trophoblastic tumor, vaginal cancer, and vulvar cancer. CGCS also updated the consensus or guidelines related to gynecological tumors, including poly(ADP-ribose) polymerase inhibitor, the use of immune checkpoint inhibitors, and the treatment of side effects. The Chinese Gynecological Cancer Multidisciplinary Team Consultation Platform, led by CGCS, has been participated by 149 hospitals across the whole country. CGCS is committed to the capacity building of Chinese gynecologic oncologists and CACA certification and cultivation of young fellows in clinical and fundamental research in gynecologic cancer. CGCS also pays attention to the popularization and education of patients and has issued guidelines for patients with gynecological cancer. CGCS has conducted numbers of clinical trials, especially for the indications of Chinese innovative drugs, and CGCS has also participated in many international trials [19-23].

ACTIVITIES OF TGOG, TAIWAN

TGOG was established in 2009 under the Scientific Committee of Taiwan Association of Gynecologic Oncologists (TAGO). Prof. Kung-Liahng Wang assumed the position of Chair of TGOG by President of TAGO, Prof. Ting-Chang Chang, at that time (**Fig. 1**). TGOG has conducted many retrospective multicenter studies within Taiwan and collaborated with Asian Gynecologic Oncology Group (AGOG) with a few prospective studies [24-28].

More recently, TGOG has joined several prospective interventional trials from ENGOT under different collaboration models and determined to spin out as an independent legal entity since August 2020. Through a series of process, the TGOG finally formally has stood as a non-governmental organization in Taiwan since April 11, 2021.

Cervical Committee trials, TGOG1001A and TGOG1001B, 1002, 1004, 1007 and TGOG1006/AGOG13-001 were published. TGOG1008/AGOG14-001 was terminated for low recruitment. TGOG1009S (Randomized, Double blind, Placebo-controlled Trial of Z-100 plus Radiation Therapy in Patients with Locally Advanced Cervical Cancer) and TGOG1010/ ENGOT-cx12 are ongoing.

Endometrial Committee trials, TGOG2001-2007 were published. TGOG2008-Therapeutic effect of recurrent disease in early-staged endometrial cancer is ongoing. TGOG2009/





Fig. 1. Organization chart of the first cabinet of EAGOT from November 19, 2021 till December 31 2022. President and vice president of the second cabinet of EAGOT from January 1 2023 till December 31 2023 are, Prof. Yong-Man Kim and Prof. Chyong-Huey Lai, respectively. EAGOT, East Asia Gynecologic Oncology Trial Group; CGCS, Chinese Gynecologic Cancer Society; JGOG, Japanese Gynecologic Oncology Group; KGOG, Korean Gynecologic Oncology Group; TGOG, Taiwanese Gynecologic Oncology Group.

ENGOT-en11, TGOG2010/ ENGOT-en7 and TGOG2011/AGOG21-001 TGOG2011/AGOG21-001 (Exploring the Molecular Markers of Intramucosal Endometrioid Endometrial Cancer of **Young** Women) are ongoing.

Ovarian Committee trials, TGOG3001-3005, 3007, 3008 were published. TGOG3010/ENGOTov43 and TGOG3011 (germline whole exome and low-coverage whole genome sequencing analysis in ovarian cancer) are ongoing.

Novel Therapy Committee trial, TGOG5001 (NCT02093325) - A randomized, double blind, placebo-controlled study to assess the efficacy and safety of eltrombopag as a rescue of isolated chemotherapy-induced thrombocytopenia in patients with gynecologic cancer is under review.

COLLABORATION OF JGOG AND KGOG IN CLINICAL TRIALS

In 2002, the 9th Biannual International Gynecologic Cancer Society meeting was held in Seoul, South Korea; when the first Japan-Korea Gynecologic Cancer Joint Meeting was held, and Prof. Ozols, President of GOG gave special lecture about the importance of multinational



clinical trials. Participants from both Japan and Korea pledged to take the lead in creating the scientific evidence through JGOG and KGOG. A total of 12 JGOG/KGOG Joint Meetings were held by 2012. However, there was no discussion about possible cooperative clinical studies; rather they just introduced clinical trials of their own group or treatment plan. Hindrance for collaborative clinical trials included differences in treatment protocols insurance-covered medications between the two countries, and research funding and data centers.

Toru Sugiyama, the third president of JGOG, and Byoung-Gie Kim, the third President of KGOG agreed to break away from the traditional JGOG/KGOG Joint Meeting and promote international clinical research between the 2 countries.

The first meeting for collaboration was held on April 8, 2016, at the Haeundae Grand Hotel in Busan, Korea, and KGOG and JGOG signed the contract for collaboration. It has been agreed that we refer to this as the "KJC Meeting" when it is held in Korea, and the "JKC Meeting" when held in Japan. The Data Management meeting was held on July 9, 2016 at Yonago Convention Center in Tottori, Japan. The 2nd JKC Meeting was held on November 1, 2016 at the Marriot Hotel in Tokyo and the 3rd KJC Meeting was held on April 26, 2019 at the Lotte Hotel, Busan, Korea. From the 1st to 3rd meeting, the participants were restricted to only core members of each group, and the concrete collaborative study had not been started yet.

The 4th JKC was held on July 2–3 at the Hotel Kahou in Niigata. Japan, and the 5th KJC Meeting was held at Gyeong Won Jae, Incheon, Korea on October 8–9. At these meetings, not only the president and vice president of each group, but also members of three disease committees, namely the Cervical Cancer Committee, Uterine Cancer Committee, and Ovarian Cancer Committee, were invited to discuss specific aspects of collaborative research. As a result, discussions on collaborative clinical studies progressed extensively in each committee.

The JGOG and KGOG agreed to make use of web conferences that enabled denser discussions for collaboration at each disease site.

We also agreed to invite other East Asian countries, namely the People's Republic of China and Taiwan, to join our collaborative study group.

TOWARD ESTABLISHMENT OF EAGOT

On December 12, 2019, Takayuki Enomoto, President of JGOG, Yong-Man Kim, President of KGOG, Kung Liahng Wang, President of TGOG at that time, and Xiaohua Wu, President of CGCS, gathered in Tokyo to discuss international collaboration among these four research groups. All presidents basically agreed to establish a new clinical trial group in East Asia for Asian women suffering from gynecologic cancer.

Owing to the outbreak of coronavirus disease 2019 (COVID-19) in January 2020, there was been no progress in the discussion toward the establishment of new clinical trial groups in East Asia in 2020. In contrast, collaboration between the JGOG and KGOG was prompted by the convenience of web-based meetings, and many collaborative clinical trials and registry studies have started. As the collaboration between JGOG and KGOG started successfully, there was growing momentum to establish a new clinical research group in East Asia.



At the 63rd Annual Meeting of JSGO in 2021 (Congress President: Masahide Ohmichi), the JGOG-KGOG-TGOG-CGCS Joint Web Session (Chair: Takayuki Enomoto and Yong-Man Kim) titled "Building a clinical trial network in East Asia: Present status and future perspectives" was held. In the session, Jae-Hoon Kim (President of KGOG), Chyong-Huey Lai (President of the TGOG), and Xiaohua Wu (President of the CGCS) introduced the clinical trials in their own countries and commented on the idea of building a clinical trial network in East Asia, which all the presidents agreed with.

On October 28, 2021, a web meeting was held to decide the name of the clinical trial group. The East Asian Gynecologic Oncology Trial Group was decided upon as the name. A foundation web meeting of EAGOT was held on November 19, 2021, and executive board members for 2022 were elected as follows: President: Takavuki Enomoto, Vice President: Yong-Man Kim, Councils from JGOG: Aikou Okamoto and Daisuke Aoki, Councils from KGOG: Jae-Hoon Kim and Jae Weon Kim, Councils from TGOG: Chyong-Huey Lai and Ting Chang Chang, Councils from CGCS: Xiaohua Wu and Jihong Liu. A total of 4 committees (Cervical Cancer Committee, Uterine Corpus Cancer Committee, Ovarian Cancer Committee and Translational Research Committee) were established. The purpose of EAGOT is to conduct international clinical trials in an effort to provide the best treatments to Asian women affected by gynecologic cancer (Bylaw of EAGOT version 1.0 Nov/19, 2021). In 2022, a single council web meeting was held and each committee web meeting was held twice. An onsite annual meeting was planned in 2002, but was canceled due to the pandemic of COVID-19. A council meeting was held in Seoul, Korea on February 25 in hybrid form (both on site and web), And the 1st Annual EAGOT Meeting, which was postponed from 2022, was finally held in hybrid form in Niigata, Japan on May 25–27, 2023.

FUTURE PERSPECTIVE

Promoting Precision Medicine is critical for developing new therapies unique to Asia, and translational research is essential to clinical trials. JGOG, KGOG, TGOG, and CGCS are internationally competitive clinical trial groups in translational research.

Strengthening the Academic Research Organization (ARO) function may also be essential for EAGOT to conduct unique international clinical trials, case series, and its expansion in Asia. JGOG has developed infrastructure, including data management and coordination of clinical trials, and collaborated with the Tohoku Medical Megabank Organization and the Clinical Research and Information Center to secure public funding, promote translational research, and strengthen biobanking. In the future, we need to build an integrated platform in East Asia that covers not only biological samples and clinical information but also digital pathology and multi-omic data. If each study is based on ICH-GCP and the Clinical Data Interchange Standards Consortium standard is implemented, the value of Big Data can be enhanced by utilizing them.

In an investigator-initiated clinical trial using an unapproved drug in EAGOT, negotiations with regulatory authorities in each country are also a challenge, as simultaneous approval in four countries is aimed at. For this purpose, it is necessary to advance negotiations with AROs and industry in each country and promote the harmonization of regulations in the four countries. However, Quality Management Systems have not yet been developed on an international scale. Developing common protocols and procedures, and implementing on-the-job training within the framework of EAGOT would be a good steppingstone.



Establishment of EAGOT, the largest healthcare/investigational innovation network in Asia in the area of gynecologic cancers, will become a platform for establishing a standard of care and leading to guidelines for Asian people. Furthermore, harmonization of regulatory/ investigator-initiated clinical trials, simultaneous approval of unapproved drugs in four countries under a common protocol, and expansion of indications would improve the prognosis of gynecologic cancers in Asia.

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