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Shanghai Gynecologic Oncology Group's consensus on the academic and industry's clinical trial types

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Shanghai Gynecologic Oncology Group (SGOG, www.ShanghaiGOG.org),[1] established in 2009, is a non-profit organization of clinical research and the full member of Gynecology Cancer Intergroup (GCIG) since 2012. It was guided by Drs. Jinghe Lang (China), Gavin Stuart (Canada) (2009-2020); Drs. Jinghe Lang (China), Ding Ma (China) (2021-) and was supported by Dr. Zeyi Cao (2009-2012). The mission of SGOG is to actively promote the investigator-initiated trial (IIT) in gynecologic cancers, particularly the innovative phase II clinical trials. Followed by the high quality of management in investigators' training, trial development, human resources, and research funding, SGOG has initiated phase III clinical trials to improve the future clinical practice. SGOG aims to obtain reliable data by conducting systematic, standardized, and high-quality clinical trials, to guide the clinical practice of ovarian cancer, endometrial cancer, and cervical cancer in China. SGOG holds group meetings twice a year, and actively participates in GCIG international communication and cooperation that expands its international and

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national influence in the field of clinical research in gynecologic cancers. This coordination is not only particularly relevant between academic groups but also with national and/or international industry partners.

The current statement is a result of consensus among SGOG committees on the definition of different trial types, which are a little different from those of the European Network of Gynaecological Oncological Trial Groups (ENGOT) consensus.[2] Three types of trials have been classified as Type A, B, and C [Table 1]. As a cooperative organization among academic centers, SGOG makes efforts on Types A and B trials to identify important, clinically meaningful questions. This trial classification is primarily applicable to randomized phase III trials. The consensus text was discussed and approved by one of the SGOG committees (ovarian, endometrial, cervix, and translational).

Type A trials are initiated by academic center with clinically hypothesis-driven investigations. Entirely different from the Type C, Type A trials aim to solve a clinical question to confirm or compare a novel or unconfirmed traditional treatment with or without updated standard treatment approaches, usually irrelevant to new drugs/devices apart from those from the physicians. In the field of gynecologic oncology, surgery is one of the most important treatments. Surgeons are uniquely poised to be effective principal investigators due to the ability to identify key issues in clinics and their experience as leaders of multidisciplinary teams. The surgery related trials initiated by surgeons will answer the basic questions in clinical practice and are critically important in gynecologic oncology. The trial design, protocol, standard operating procedure (SOP), and statistical analysis plan (SAP) are developed by the leading group, then reviewed and approved by the trial steering committee. Although led by principal investigators, Type A trials are monitored by a central committee of clinical experts in a particular field.[3,4] Monitoring process is organized by the academic group. Each serious adverse event and patients' rights should be regularly reviewed by an independent data monitoring committee (iDMC). Thus, patients would receive more or comparable benefit compared to the standard of care, without any risk of new drug/device failure. More importantly, academic center has overall responsibility for the whole process of Type A trials, such as data management, quality control, and publishing. Intellectual property including database, publication, and patents, belongs to the academic center in full. So, Type A trials are characterized by academic investigator's independent innovation. Unlike those in ENGOT types, to date, SGOG did not include any drug trials in the Type A.

Type C trials are completely sponsored and initiated by industry partners with the purpose of new drug/device application. With sufficient funding support, Type C trials tend to recruit more study groups and even international multicenter participation for the high-level evidence of new drugs or devices. The study design, protocol, SOP, SAP, and even manuscript drafting are coordinated by the industry company. Considering the purpose of drug/device approval, governments such as US Food & Drug Administration and Chinese National Medical Products Administration, have regulatory requirements for the new drug use depending on the rigor of prior research and intended use.[5] During the management of Type C trial,

Table 1: The three types of clinical trials agreed by SGOG.

Items	Type A	Type B	Type C
Initiated party	The academic center	The academic center	The industry
Research purpose	Hypothesis-driven investigation. To confirm or compare a novel or unconfirmed traditional treatments with or without updated standard treatment approaches, irrelevant to new drugs/devices, apart from the academic center/person owning an intellectual property right	To confirm or compare approved new drugs/devices with or without standard treatment approaches	To compare unapproved drugs/devices with standard treatment approaches
Protocol	Designed and developed by the leading study group, then reviewed and approved by the trial steering committee	Designed and developed by the leading study group and the industry partner, then reviewed and approved by the trial steering committee	Designed and developed by the industry for the approval of new drugs/devices
Independent DMC	Organized by the academic center	Organized by the academic center	Organized by the industry
Founding	Government /The academic center	Government /The academic center and industry co-funding	The industry
Patients' benefit	Compared to Type C, benefit greatly or comparably	Compared to Type C, benefit greatly or comparably, but still face the risk of drug/device failure and potential adverse events	Benefit greatly or failure, and potential adverse events
Database property	The academic center	CRO contracted by the academic center	CRO contracted by the industry
Intellectual property	The academic center	Partially belong to the academic investigators	The industry

CRO: Contract research organization; DMC: Data monitoring committee; SGOG: Shanghai Gynecologic Oncology Group.

the sponsor company must receive all the information needed for pharmacovigilance and maintain the global safety reporting for the database at the contract research organization (CRO). Serious adverse events should be regularly reviewed by the steering committee and the iDMC. As a result, patients may benefit greatly from novel drugs/devices, but sometimes must take the risk of drug failure and potential adverse events. The industry occupies intellectual property entirely.

To improve the cooperation of the academic center and industry partners, number of Type B trials has been increased during the recent years. SGOG believes Type B model might be important for the future clinical and translational research on newly approved drugs/devices in gynecologic cancers and, probably, also for the high-level evidence of drug efficacy and safety.

Requirements for Type B trials:

i. Trials initiated by a leading academic center.

ii. Study protocol, SOP, and SAP are designed and developed by both the academic center and industry partners.

iii. Monitoring is preferably organized by the academic group. Both the academic center and industry companies must receive all the information needed for pharmacovigilance. Serious adverse events should be regularly reviewed by steering committee and an iDMC.

iv. The database is independently generated and managed at CRO, which is preferably contracted by the leading group. Neither the study group nor the industry has access to the database regarding primary and key secondary endpoints before the time of pre-planned analysis. The study group is responsible for the use of database for educational and scientific purposes, irrespective of who is the sponsor.

v. Funding could be derived from both government/the academic center and the industry company.

vi. Patients may benefit greatly or comparably from new approved drugs/devices, but still face the risk of drug/device failure and potential adverse events.

vii. The leading study group is responsible for the independent analysis for primary and secondary endpoints. The official study report, publication, or patents must be agreed by the leading study group.

viii. A contract needs to be agreed upon between the industry partner and the leading study group, as well as between the industry partner and cooperating groups.

ix. Intellectual property partially belongs to the academic center.

This consensus did not discuss the questions of the database and relationship with the contract research organizations.

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References

1. SGOG, www.ShanghaiGOG.org.
2. du Bois A, Reuss A, Pujade-Lauraine E, Pignata S, Ledermann J, Casado A, *et al*. European Network of Gynaecological Oncological Trial Groups' Requirements for Trials Between Academic Groups and Industry Partners--First Update 2015. *Int J Gynecol Cancer* 2015;25:1328–1330.
3. Park KU, Mamounas EP, Katz MHG, Unzeitig G, Carpizo D, You YN, *et al*. Clinical Trials for the Surgical Oncologist: Opportunities and Hurdles. *Ann Surg Oncol* 2020;27:2269–2275.
4. McDonald HG, Cassim EB, Harper MM, Burke EE, Marcinkowski EF, Cavnar MJ, Pandalai PK, Kim J. The Development of Investigator-Initiated Clinical Trials in Surgical Oncology. *Surg Oncol Clin N Am*. 2023;32:13–25.
5. FDA. New Drug Development and Review Process. 2023/07/31. https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/new-drug-development-and-review-process.

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