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How to optimize and evaluate diversity in gynecologic cancer clinical trials: statements from the GCIG Barcelona Meeting

Jalid Sehouli ,[1,2] Jolijn Boer ,[2] Alison H Brand,[3,4] Amit M Oza,[5] Jennifer O'Donnell,[4] Katherine Bennett,[4] Ros Glaspool,[6] Chee Khoon Lee,[7] Josee-Lyne Ethier ,[8] Philipp Harter ,[9,10] Veronika Seebacher-Shariat,[11,12] Ting-Chang Chang,[13,14] Paul A Cohen ,[15] Toon van Gorp ,[16] Adriana Chavez-Blanco,[4] Stephen Welch,[17] Hanna Hranovska,[18] Sharon O'Toole ,[19] Christianne A R Lok ,[20] Ainhoa Madariaga ,[21,22] Jose Alejandro Rauh-Hain,[23] Alejandro Perez Fidalgo ,[24] David Tan ,[25] Judith Michels,[26,27] Bhavana Pothuri,[28] Noriko Fujiwara ,[29,30] Ora Rosengarten,[31] Hiroshi Nishio,[32,33] Se Ik Kim,[34] Asima Mukopadhyay,[35] Elisa Piovano,[36] Sabrina Chiara Cecere,[37] Elise C Kohn,[38] Uma Mukherjee,[39] Sara Nasser,[40,41] Kristina Lindemann ,[42,43] Jennifer Croke,[44] Xiaojun Chen,[45] Franziska Geissler,[46,47] Michael A Bookman[4,48]

ABSTRACT

Findings from clinical trials have led to advancement of care for patients with gynecologic malignancies. However, restrictive inclusion of patients into trials has been widely criticized for inadequate representation of the real-world population. Ideally, patients enrolled in clinical trials should represent a broader population to enhance external validity and facilitate translation of outcomes across all relevant groups. Specifically, there has been a systematic lack of data for underrepresented groups, with many studies failing to report or differentiate study participants based on sociodemographic domains, such as race and ethnicity. As such, the impact of treatment in these underrepresented groups is poorly understood, and clinical outcomes according to various sociodemographic factors are infrequently assessed. Inclusion of diverse trial participants, with different racial and ethnic background, is essential for the understanding of factors that may impact clinical outcomes. Therefore, we conducted a multinational meeting of clinical trial groups and industry with the goal of increasing equity, diversity, and inclusion in gynecologic cancer clinical trials and to address barriers to recruitment, participation, and harmonization of data collection and reporting. These Gynecologic Cancer Intergroup (GCIG) statements present recommendations and strategies for the gynecologic cancer research community to improve equity, diversity, and inclusion in gynecologic cancer clinical trials.

BACKGROUND

Findings from clinical trials have led to improvement in the standard of care and survival of patients with cancer, including those with gynecologic malignancies.[1] However, most studies have restrictive inclusion of patients which often inadequately represent the wider populations, limiting our ability to translate clinical trial findings across diverse groups of patients seen in routine daily practice. In parallel, there is a systematic lack of data capture and reporting for the underrepresented groups resulting in significant data gap in outcomes of patients with gynecologic cancer from diverse background.[2–4] Studies in the United States indicate that the average trial participant tends to be younger, have higher levels of education, have less ethnic diversity, and have fewer concurrent medical conditions compared with the general population of patients with the respective disease.[5–10]

Several studies report the impact of various sociodemographic domains on clinical outcomes, yet harmonization of measures as well as evidence regarding how these domains intersect are missing.[11 12]

In 2015, Ramamoorthy et al, showed that around 20% of authorized new drugs vary in terms of safety, efficacy, dosage, pharmacokinetics, or pharmacogenetics between different races and ethnicities. To provide accurate instructions, such as dosage adjustments or precautions, it is critical to recognize disparities between underrepresented groups, such as those based on race and ethnicity, early in the drug development process.[13]

Despite recognition of the importance of diversity in pivotal clinical trials for new drugs, as outlined in 2015 by the United States Food and Drug Administration's (FDA) 5 year action plan, black patients continue to be underrepresented in clinical trials, with enrollment rates, reporting of treatment benefits and reporting of side effects remaining low.[14] Interviews with healthcare professionals show that people from underrepresented groups often tend to be skeptical about participating in clinical trials. In addition, numerous barriers, especially financial and language barriers hinder clinical trial participation for these groups.[15 16]

There is a compelling need for change and this issue is widely recognized by many leading research organizations, including the Gynecologic Cancer Intergroup (GCIG), American Society of Clinical Oncology (ASCO) and WHO as well as national professional

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For numbered affiliations see end of article.

Correspondence to
Professor Jalid Sehouli; jalid.sehouli@charite.de

JS and JB are joint first authors.

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societies, all committed to establishing fairer and more accessible clinical trials for all cancer patients.[17 18] The GCIG is a global consortium founded in 1997 and made up of 33 research groups from Asia, North America, South America, Europe and Australia conducting clinical trials in gynecologic cancers. GCIG's membership also includes Liaison Members, partners from the pharmaceutical and biotechnology industries, and the National Cancer Institute.[19] An important initiative of the GCIG is the Cervical Cancer Research Network, which collaborates with sites in low- and middle-income countries to boost patient representation in clinical trials from underrepresented areas such as Latin America, Africa, and the Indian subcontinent.[20] The GCIG Equity, Diversity and Inclusion Meeting was convened during the Spring 2024 GCIG Meeting in Barcelona, with special focus on racial and ethnic diversity. The main objectives were to address barriers that might prevent individuals from participating in trials, as well as harmonization of data collection and reporting to facilitate international collaboration. For the very first time, the GCIG developed clear statements with specific recommendations and strategies aimed at promoting equity, diversity, and inclusion within the research community and improving the landscape of gynecologic cancer clinical trials.

METHODS

The GCIG Meeting focused on two key issues: formulating strategies to encourage participation of underrepresented groups in clinical trials and defining a minimal required dataset to facilitate international harmonization in data capture, reporting and collaboration. Each of the 33 participating GCIG member groups appointed delegates to participate in the GCIG Barcelona Meeting (for a list of participants, see Online Supplemental Table 1). The preparatory work for the meeting included a thorough literature review and three joint meetings of an interdisciplinary and interprofessional scientific committee (AB, AO, JB, JO, JS, KB, MB). These efforts were complemented by findings from a customized questionnaire distributed among the GCIG groups to assess the status quo of equity, diversity and inclusion in hospitals from different countries, referred to in this report as the 'NOGGO-GCIG-IDEA survey'. The results of the 'NOGGO-GCIG-IDEA survey' will be reported separately. This preliminary work formed the basis for a plenary session, which was enriched by the appointment of specialist speakers and discussants. The key references, on which the statements were based, were carefully selected from a comprehensive list of clinical trials in gynecologic cancers and also wider literature searches. Transparency was maintained throughout the conference by presenting all references to participants for review, facilitated by the moderation of the co-chairs of each topic group. The plenary session discussed a wide range of viewpoints on equity, diversity, and inclusion in clinical trials, encompassing perspectives from an individual with lived experience, a representative from a major pharmaceutical company, clinicians and researchers from Europe, Africa, Asia, Australia, North and South America, as well as insights from global organizations such as the WHO, the GOG Foundation, the European Medicines Agency and the FDA. The speakers were from five continents representing Asia (India, Taiwan, Lebanon), Australia, Europe (Germany, Sweden), North America (United States of America), and South America (Mexico). Following the plenary discussions, the meeting split into two working groups tasked with producing these statements. The session concluded with an in-depth discussion of the working groups' findings, fine-tuning the statements in preparation for adoption by the participants and ensuring that the GCIG's collective voice was both resonant and representative. In addition, an endorsement from the European Society of Gynecologic Oncology was received for the recommendations.

Box 1 GCIG statements: Actions to increase patient numbers from underrepresented groups in clinical trials.

Statements

1. All trials should be inclusive. The GCIG is committed to increasing representation in clinical trials (including, but not limited to age, gender, socioeconomic status, geographic regions, race, ethnicity, physical ability, and sexual orientation).
2. Inclusion criteria should be broadened to increase the generalizability of findings that will be applicable to the real-world population.
3. A minimal required dataset should be collected and reported to measure improvements in the representativeness of clinical trial participants.
4. Patient-centered communication should be enhanced with special emphasis on diversity and cultural sensitivity.
5. The informed consent process should be adapted wherever possible, only include essential items and be developed in collaboration with individuals with lived experience.
   i. *Consider the creation of a GCIG consent template in the most frequently spoken languages and non-written formats.*
6. The inconvenience of trial participation for patients should be reduced.
   i. *This includes provision of financial support for patients, working with community hospitals, streamlining of visits and investigations where appropriate.*
2. The adoption of proposed recommendations through engagement with key stakeholders such as government agencies and industry partners should be ensured.

RESULTS

Focus Topic A: Actions to increase patient numbers from underrepresented groups in clinical trials

The GCIG statements on how to increase the number of patients from underrepresented groups in clinical trials for gynecologic cancers are summarized in Box 1.

Statement 1: All trials should be inclusive. The GCIG is committed to increasing representation in clinical trials (including, but not limited to age, gender, socioeconomic status, geographic regions, race, ethnicity, physical ability, and sexual orientation)

To enhance the inclusivity and validity of clinical trials, particularly in the realm of gynecologic cancers, it is imperative to focus on the integration of underrepresented groups.[21 22] These groups are diverse and context-specific, impacted by region, study design, and available resources. For instance, depending on the setting, trial population representation might be limited according to ethnic minorities, or specific age groups, adequate radiation facilities, tumor molecular profiles, or socio-economic status. Recognizing and defining these underrepresented groups within the context of each clinical trial is a foundational step toward ensuring their

adequate inclusion. Following the FDA's proposal , the GCIG recommends that clinical trial sponsors submit a plan to increase representativeness in clinical trials (including, but not limited to age, gender, socioeconomic status, geographic regions, race, ethnicity, physical ability, and sexual orientation) before the start of phase III trials.[23] Nevertheless, we recommend that diversity be prioritized even in phase I and II trials.

Statement 2: Inclusion criteria should be broadened to increase the generalizability of findings that will be applicable to the real-world population

A meta-analysis found that more than 50% of cancer patients refrain from participating in clinical trials because their medical institution does not have trials tailored to their specific cancer type or stage. Even when trials are available, over 20% of patients are unable to participate due to exclusion criteria.[24] Willingness to participate is similarly high across all racial and ethnic groups, including black, Hispanic, Asian, and white patients.[25] Inclusion criteria are often too restrictive, thus enriching clinical trials with low-risk populations.[26] Exclusion criteria can limit participation by individuals with compromised physical health or mobility, those under 18, older individuals, or those with specific coexisting conditions like organ dysfunction or HIV/AIDS.[26 27] Individuals from diverse backgrounds are also often excluded due to specific language requirements associated with informed consent. Broadening the inclusion criteria will increase generalizability of clinical trials, particularly with phase III studies, such that the trial populations will reflect the real-world patients.[28] Consistent with ASCO and Friends of Cancer Research, the GCIG recommends broadening inclusion criteria before clinical trial activation or considering expanding the study population during the conduct of a clinical trial.[27] Enabling healthcare professionals and individuals with lived experience from diverse backgrounds to participate in trial design, with an emphasis on inclusion criteria, could effectively address significant gaps in research inclusivity.

Statement 3: A minimal required dataset should be collected and reported to measure improvements in the representativeness of clinical trial participants

The GCIG recommends the use of standardized variables, including race and ethnicity, in the form of a minimal required dataset when collecting and reporting data from clinical trials. This approach should be underpinned by a thorough review of existing data and maximizing the statistical power to examine the impact of various diversity factors – such as ethnicity, age, socioeconomic status and comorbidities – on clinical outcomes. Harmonization of the dataset collected internationally across all studies will enable more effective subgroup analyses and comparisons across studies. Ideally, a universally agreed method of data collection should be compliant with guidelines from regulatory agencies. The consistency of these categories is crucial as it helps to assess any differences in the safety and efficacy of drugs between different groups of people.[23] In addition, the development of a flexible toolkit of data elements would accommodate the different objectives of different studies and allow researchers to select data elements that best fit their specific research questions. The use of a minimal required dataset is also important to measure improvements in the representation of participants in clinical trials.

Statement 4: Patient-centered communication should be enhanced with special emphasis on diversity and cultural sensitivity

A study conducted by Swaby et al, showed that one of the most important factors for the low participation of African Americans in cancer clinical trials is mistrust of the treating oncologist.[29] Approximately 50% of cancer survivors belonging to an underrepresented group state that it is important to them that their doctor knows or understands their cultural background.[30] Patel et al, proposed that employing lay or community health worker-led interventions could enhance the involvement of underrepresented cancer patients in clinical trials, potentially attributed to shared backgrounds and experiences.[31] Fouad et al, studied the effectiveness of patient guides, who were trained by a team of culturally diverse healthcare professionals, in educating and supporting patients during clinical trials. Their research revealed that utilizing these patient guides resulted in a significant increase in the participation of African American patients in clinical trials.[32] Other studies also suggest that the use of patient guides, the cultural and linguistic adaptation of marketing materials and the use of online computer programs addressing barriers to clinical trials are effective approaches to increasing the enrollment of underrepresented minorities in cancer clinical trials.[33 34] The GCIG advocates for training healthcare professionals and individuals with lived experience on equity, diversity, inclusion, and access, believing it will enhance communication, trust, and understanding between researchers and participants from underrepresented groups. Ensuring that medical staff and individuals with lived experience come from diverse backgrounds, and that patient informed consent forms are concise, readable, and approved by individuals with lived experience, can significantly improve the inclusivity and effectiveness of clinical trials. Additionally, we recommend future trials to evaluate these interventions on their long-term efficacy.

Statement 5: The informed consent process should be adapted wherever possible, only include essential items and be developed in collaboration with individuals with lived experience

Language barriers significantly hinder the participation of migrant populations in clinical trials.[35] A study that analyzed the inclusion and exclusion criteria for studies on endometrial cancer found that non-English speakers were excluded from participation in 1 in 10 studies conducted between 1998 and 2021.[36] To counteract this problem, informed consent documents and patient-reported outcome forms should be available in the most commonly spoken languages among the target population.[37] Furthermore, the development of study materials and guidelines should involve individuals with lived experience to ensure that patient needs and perspectives are adequately represented. The creation of a GCIG consent template in the most frequently spoken languages and non-written formats should be considered. The use of professional translators and emerging artificial intelligence (AI) based translation tools should also be explored to further reduce barriers and enhance patient engagement.

Statement 6: The inconvenience of trial participation for patients should be reduced

To foster an environment that encourages the participation of diverse patient groups, clinical trials must prioritize convenience

and accessibility. This includes minimizing the number of additional in-person visits required for trial participation, and employing additional communication methods such as video consultations. Andriani et al, point out that the use of telemedicine and remote clinical trials in gynecologic oncology studies are deemed safe and do not compromise compliance with clinical trial protocols.[38] Additionally, integrating community clinicians into clinical research initiatives could alleviate accessibility barriers for patients, such as work and other daily schedules and transportation.[39] Offering and providing transportation, meal vouchers, childcare support, or other financial reimbursement can also significantly affect patient participation in clinical trials, with appropriate attention to avoid unintended coercion.[40–42]

Statement 7: The adoption of proposed recommendations through engagement with key stakeholders such as government agencies and industry partners should be ensured

Engaging with regulatory authorities and incorporating a broader understanding of diversity – including distinctions between sex and gender, as well as the inclusion of the lesbian, gay, bisexual, transgender, queer or questioning+ (LGBTQ+) population – are crucial considerations. Clinical research forms should encompass socio-cultural elements for planned subgroup analyses, taking into account regional disease prevalence and patient perspectives, including insights from individuals with lived experience. A unified approach by regulatory authorities could streamline the informed consent process across different regions, making it easier for patients to understand their involvement and rights within a trial. Including best supportive care options, ensuring insurance coverage, and building patient trust are also vital components of patient-centered clinical trial design.

Focus Topic B: Defining a minimal required dataset for clinical trials

The GCIG statements on defining a minimal required dataset for clinical trials are summarized in Box 2. The selection of the individual items should be defined in the context of the primary and secondary endpoints.

Statement 1: Consented, self-reported race, ethnicity and geographical site should be collected in every trial

In line with the FDA's proposal and the results of studies examining discrepancies between self-reporting and hospital staff documentation, the GCIG recommends study participants to self-report their race and ethnicity rather than the study team assigning race and ethnicity.[23 43 44] If self-reporting is not possible, this information should be obtained from an immediate family member or other reliable source. Additionally, study participants should have the opportunity to declare a multiracial identity whenever applicable.[23] Separate consent to provide racial identity and the option to opt out should be provided. In cases where participants are unsure of their ancestry because they are orphans, adopted or unaware of their true origins, guidance should be included in the consent process on how to deal sensitively with such situations. The geographical site, which refers to the patient's place of birth and the parents' place of birth, should be collected in every trial to assess migration background.[45] All questions should be culturally sensitive and legally acceptable in individual countries and jurisdiction. As such, disaggregated data can be collected but subsequently combined in internationally agreed categories.

Box 2 GCIG statements: Defining a minimal required dataset for clinical trials.

Statements

1. Consented, self-reported race, ethnicity and geographical site should be collected in every trial
   i. More than one option should be allowed.
   ii. Questions should be culturally sensitive and legally acceptable in individual countries. As such, disaggregated data can be collected but subsequently combined in internationally agreed categories.
   iii. Separate consent with the option to opt out is required.
2. Social determinants of health should be included in the minimal required data set
   i. Socioeconomic status (eg, education)
   ii. Standard of living index (eg, access to food, water, environmental exposure)
   iii. Access to care
3. Measures of performance status, comorbidities, and frailty should be included in a minimal required dataset
   i. Consideration should be given to including people with Eastern Cooperative Oncology Group (ECOG) performance status greater than 1.
   ii. Restrictive eligibility criteria for trials should only be included where there is evidence that they are required for safety.
4. Consented, self-reported data on sexual orientation, sex at birth and gender identity should be collected
   i. Separate consent with the option to opt out is required.

Statement 2: Social determinants of health should be included in the minimal required dataset

Social determinants of health should be included in the minimal dataset, taking into account the feasibility, utility and acceptability of such data collection, especially in the context of international studies that have to deal with different living standards and health systems. There is a need to use simple assessment systems that can be applied across countries, particularly between high-, middle-, and low-income countries. As a measure of socioeconomic status, educational level is preferable due to its strong correlation with health inequalities, its standardized assessment and its ability to capture lifestyle factors.[45] Surrogates could also be used, such as the use of postcodes in the UK as a measure of social deprivation, or the use of a standard of living index and access to care to measure social determinants of health efficiently and consistently.

Statement 3: Measures of performance status, comorbidities, and frailty should be included in a minimal required dataset

While measures of performance status, comorbidities and frailty should always be included in a minimal dataset, the focus and specific elements included should be defined according to context. When selecting elements, it is important to consider that, for example, ECOG performance status alone does not fully capture the true comorbid status of patients, leading to potentially significant differences in treatment effects even between those with the same performance status; ECOG performance focuses primarily on physical function and does not take into account the complexity and

impact of various comorbidities.[46] Therefore, consideration should be given to including people with ECOG performance status greater than 1. A study evaluating study protocols of oncology trials found that only 35% of trials included patients with ECOG performance status greater than 1. Less than 1% of trials included patients with ECOG performance status greater than 2,[26] which is clearly not representative of patient populations in clinical practice. Additionally, the GCIG recognizes the need to address the inclusion of participants with mental health issues, who have historically been excluded due to consent concerns. The GCIG emphasizes that, along with the joint ASCO and Friends of Cancer Research statement, restrictive eligibility criteria relating to performance status, co-morbidities, frailty, and mental health status should only be included for clinical trials where there is a safety consideration of the study treatment.[47]

Statement 4: Consented, self-reported data on sexual orientation, sex at birth and gender identity should be collected

Several trials underline the importance of people undergoing gender-affirming hormone therapy experience physiological changes, such as alterations in muscle and fat distribution.[48 49] Cheung et al, showed that it is important to consider these changes when interpreting gender-specific laboratory tests.[50] Based on the proposal by Stadler et al, to list gender-diverse options when identifying gender, a question about gender at birth should also be asked, but only if it is relevant to the research. Survey instruments on sexual orientation should list different sexual orientations and recognize fluidity.[45] Separate consent and the option to opt out should be provided for all questions. In addition, there is a particular need for further and advanced training in this area. To ensure respectful and accurate collection of this data, comprehensive and ongoing training of clinicians and data collectors is critical. This training must focus on understanding and overcoming personal biases, fostering an inclusive and supportive environment, and communicating effectively with participants about sensitive topics.

CONCLUSION

Through these recommendations, we aim to minimize barriers for underrepresented groups to participate in clinical research, including international harmonization of data collection and reporting. It is our hope that these guidelines will be adopted by GCIG Member Groups and pharmaceutical sponsors as new studies are developed. We acknowledge that the selection of delegates for the GCIG Barcelona Meeting may have potentially influenced the outcomes, as specific diversity data were not collected post hoc. Moving forward, we will systematically incorporate the collection and consideration of diverse perspectives, ensuring that future development and implementation of our statements reflect the input of individuals from varied backgrounds and experiences. We also look forward to further refinement of these guidelines in collaboration with the medical and non-medical communities to achieve our goal of personalized medicine and equal opportunities for all patients with gynecologic cancers to participate in clinical trials.

Author affiliations
[1]Gynecology with Center for Oncological Surgery, Charite Universitatsmedizin Berlin, Berlin, Germany
[2]North-Eastern German Society of Gynaecological Oncology (NOGGO eV), Berlin, Germany
[3]Westmead Hospital, Westmead, New South Wales, Australia
[4]The Gynecologic Cancer InterGroup, Kingston, Ontario, Canada
[5]Medical Oncology & Hematology, Princess Margaret Hospital Cancer Centre, Toronto, Ontario, Canada
[6]Beatson West of Scotland Cancer Centre, Glasgow, UK
[7]NHMRC Clinical Trials Centre, The University of Sydney, Camperdown, New South Wales, Australia
[8]Division of Medical Oncology, Odette Cancer Centre, Sunnybrook Health Sciences Centre, Toronto, Ontario, Canada
[9]Gynecology and Gynecologic Oncology, Kliniken Essen-Mitte Evangelische Huyssens-Stiftung/Knappschaft GmbH, Essen, Germany
[10]AGO Study Group, Wiesbaden, Germany
[11]AGO Austria, Innsbruck, Austria
[12]Medical University of Vienna, Vienna, Austria
[13]Linkou Chang Gung Memorial Hospital, Taoyuan, Taiwan
[14]Chang Gung University, Taoyuan, Taiwan
[15]Australia New Zealand Gynaecological Oncology Group (ANZGOG), Camperdown, New South Wales, Australia
[16]Gynaecological Oncology, KU Leuven University Hospitals Leuven, Leuven, Belgium
[17]Department of Oncology, Western University Schulich School of Medicine & Dentistry, London, Ontario, Canada
[18]National Academy of Medical Sciences of Ukraine, Kiiv, Ukraine
[19]Cancer Trials Ireland, Dublin, Ireland
[20]Department of Gynaecologic Oncology, Netherlands Cancer Institute, Amsterdam, Noord-Holland, The Netherlands
[21]12 de Octubre University Hospital, Madrid, Comunidad de Madrid, Spain
[22]European Organisation for Research and Treatment of Cancer, Brussels, Belgium
[23]The University of Texas MD Anderson Cancer Center, Houston, Texas, USA
[24]Medical Oncology, Hospital Clinico Universitario, Valencia, Spain
[25]National University Cancer Institute, Singapore
[26]Gustave Roussy, Villejuif, Île-de-France, France
[27]Université Paris-Saclay, Villejuif, Île-de-France, France
[28]NYU Langone Health Perlmutter Cancer Center, New York, New York, USA
[29]Department of Palliative Medicine and Advanced Clinical Oncology, IMSUT Hospital of the Institute of Medical Science, The University of Tokyo, Minato-city, Tokyo, Japan
[30]Gynecologic Oncology Trial and Investigation Consortium (GOTIC), Moroyama, Japan
[31]Medical Gyneco-Oncology Unit, Shaare Zedek Medical Center, Jerusalem, Jerusalem, Israel
[32]Department of Obstetrics and Gynecology, Keio Univesity School of Medicine, Tokyo, Japan
[33]Japanese Gynecologic Oncology Group (JGOG), Tokyo, Japan
[34]Obstetrics and Gynecology, Seoul National University Hospital, Seoul, Korea (the Republic of)
[35]Kolkata Gynecological Oncology Trials and Translational Research Group (KolGOTrg), Kolkata, India
[36]Azienda Ospedaliero Universitaria Citta della Salute e della Scienza di Torino, Torino, Piemonte, Italy
[37]Dep. of Experimental Uro-Gynecological Oncology, National Cancer Institute Institute for Hospitalization and Care Scientific Foundation Pascale, Naples, Italy
[38]Clinical Investigations Branch, Cancer Therapy Evaluation Program, National Cancer Institute, Rockville, Maryland, USA
[39]GynaeOncology Trials Group UK (GCG UK), London, UK
[40]Department of Gynecology with Center of Oncological Surgery, Charite Universitatsmedizin Berlin, Berlin, Germany
[41]Pan-Arabian Research Society of Gynecological Oncology, Berlin, Germany
[42]Department of gynecological oncology, Oslo University Hospital, Oslo, Norway
[43]Nordic Society of Gynaecological Oncology (NSGO), Copenhagen, Denmark
[44]Princess Margaret Hospital Cancer Centre, Toronto, Ontario, Canada
[45]Tongji University Dongfang Hospital, Shanghai, Shanghai, China
[46]Department of Gynecology and Gynecological Oncology, Hospital for Women, University Hospital Basel, Basel, Switzerland

[47]Swiss GO Trial Group, Basel, Switzerland
[48]Kaiser Permanente Northern California, Oakland, California, USA

X Josee-Lyne Ethier @joseelyneMD, Sharon O'Toole @shotoole81 and Ainhoa Madariaga @AinhoaMada

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ORCID iDs
Jalid Sehouli http://orcid.org/0000-0002-5963-6623
Jolijn Boer http://orcid.org/0009-0009-0873-4686
Josee-Lyne Ethier http://orcid.org/0000-0003-0711-1021
Philipp Harter http://orcid.org/0000-0002-9663-5005
Paul A Cohen http://orcid.org/0000-0002-4860-9232
Toon van Gorp http://orcid.org/0000-0002-2564-721X
Sharon O'Toole http://orcid.org/0000-0002-9260-3225
Christianne A R Lok http://orcid.org/0000-0001-8693-7299
Ainhoa Madariaga http://orcid.org/0000-0001-7166-9762
Alejandro Perez Fidalgo http://orcid.org/0000-0003-3568-4345
David Tan http://orcid.org/0000-0001-9087-5262
Noriko Fujiwara http://orcid.org/0000-0001-8201-9490
Kristina Lindemann http://orcid.org/0000-0002-2162-0175

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