For the QOL assessment, the results from approximately 300 subjects accumulated during the first 2 years after the start of study will be published initially. All registered subjects from whom informed consents were obtained will be subject to cost-effectiveness analysis, and the publication of the results will be performed after the completion of primary endpoint analysis due to the requirements of data on PFS and OS.

13.3.2 Phase II part 2

13.3.2.1 Analysis sets

A feasibility analysis of study treatment will be performed on subjects who have received at least one dose of study treatment.

13.3.2.2 Feasibility analysis

The number of subjects completing treatment, hematotoxicity, and non-hematotoxicity will be compiled in each arm and these occurrence rates will be predicted. In addition, adverse events rates and response rates in subjects with evaluable lesions will be compiled for each arm. An exact 95% confidence interval will be calculated for each rate. As backup materials for the decision whether to continue the study by the Independent Data Monitoring Committee, the odds ratio in each arm will be calculated, together with the p-values using Fisher's exact test and the 95% confidence interval for the odds ratio based on the normal approximation.

14 ETHICS

14.1 Ethical conduct of the clinical trial

All investigators associated with this clinical trial must conduct the study in accordance with the Declaration of Helsinki 【See Appendix 3-I】.

This clinical trial must be conducted in accordance with the Ethical Guidelines for Clinical Studies and should follow "Good Clinical Practice (GCP) guidelines."

The rights, safety, and well-being of the trial participants are the most important considerations and should take precedence over the interests of science and society.

14.2 Patient information and informed consent

Prior to registration, investigators will provide patients with the informed consent documents shown in Appendix2-① or other written documents approved by the Institutional Review Board (IRB) Independent Ethical Committee (IEC) and explain the following in detail:

1) Diagnosis and current condition;
2) This study is a clinical trial. The difference between a clinical trial and clinical practice;
3) The rationale, significance, necessity, and objectives of this study;
4) The content of protocol treatment;
5) The name of drugs, route of administration, dosage, treatment cycles, and duration of the overall protocol treatment;
6) The design of the clinical trial: This is a randomized phase II/III trial;
7) The reasonably expected benefits from protocol treatment;
8) The reasonably foreseeable toxicities (adverse events): in particular, expected adverse drug reactions induced by the IP therapy;
9) Possibilities of treatment-related death and other adverse sequelae;
10) The content of general practice (including palliative therapy) and standard treatment, and associated benefits and toxicities;
11) The benefits and disadvantages possibly arising from participation in the study;
12) The alternative treatments;
13) The benefits and disadvantages arising from alternative treatments;
14) That not giving consent for participation in the study will not cause any disadvantage to patients;
15) Patients may withdraw informed consent after giving it without being disadvantaged in any way;
16) The human rights of patients will be protected;
17) The confidentiality of the patient's name and personal information will be maintained;
18) The patient is free to ask questions regarding this trial of the investigators and the institutional principal investigator, as well as the iPocc Trial Coordinating Center by providing their contact information in writing.
19) The approximate planned number of patients to be involved in this clinical trial;
20) Patients will be informed in a timely manner if information becomes available that may be relevant to the patient's willingness to continue participation in the clinical trial;
21) Costs for the treatment and compensation for health injury: an example on cost burden on patients in both arms, the content of compensation, and information on clinical trial insurance (liability insurance);

22) Agreement to the direct inspection and audit of the patient medical record
23) The conflicts of interest related to this clinical trial;
24) The clinical trial registration in the University hospital Medical Information Network-clinical registration (UMIN-CTR) and National Network of Libraries of Medicine (NLM).

14.3 Patient's consent

When an explanation of the study is provided to the patient (or the patient's legally authorized representative who is able to give consent on behalf of the patient) regarding his/her participation in the study, it is necessary to confirm that he/she fully understands the content of the study. In particular, for this study, sufficient explanation of the following must be given: 1) the possibility of adverse drug reactions induced by the IP therapy, 2) the difference in cost burden on patients between the arms, 3) that no monetary compensation will be provided for chemotherapy-related injury; however, prompt medical care will be provided, and this clinical trial is covered by clinical trial insurance; 4) conflicts of interest, and 5) that the clinical trial is registered at the UMIN in Japanese and at the NLM in English. When the patient agrees to participate in the trial, the patient and the Investigator who has provided an explanation of the trial must date and sign on the IRB approved consent form【See Appendix 2-①】. Informed consent must be obtained in writing.
A signed copy of the form must be given to the patient. The original consent must be retained in the clinical records of the institution.

14.4 Privacy protection and patient identification

The names of registered patients will not be revealed to the iPocc Trial Coordinating Center by the participating institutions. The identification of, and inquiries regarding, registered patients will be conducted using a protocol patient ID number assigned at the time of registration and the initials of patients.

14.5 Compliance with the protocol

Investigators participating in this clinical trial must conduct the study in compliance with the protocol to the extent that the patient's rights and safety are protected.

If noncompliance with the protocol is identified by monitoring or auditing processes, such noncompliance will be considered to be a "protocol deviation" or "protocol violation" based on the degree of noncompliance. When investigators determine that it is difficult to treat the patient in compliance with the protocol for any reason, they must contact the iPocc Trial Coordinating Center for further instructions.

If serious non-compliance with the ethical guidelines is discovered, the opinions of the IRB at the relevant institution must be sought, and the results should to be reported to the Minister of Health, Labour and Welfare (MHLW). The reporting procedures are as described in the section "Specifications in Ethical Guidelines" under 11.5.1. Serious non-compliance with ethical guidelines will be disclosed to other participating institutions, after review by the IDMC.

14.6 Approval by the Institutional Review Board (IRB)/Institutional Ethics Committee (IEC)

Prior to participation in this clinical trial, the protocol and informed consent documents must be approved by the IRB/IEC. When IRB/IEC approval is granted, the investigator at each institution will fax a copy of the certificate of IRB/IEC approval to the iPocc Trial Coordinating Center.

In addition, notification of acceptance of ESIMeC needs to be faxed to the iPocc Trial Coordinating Center. The originals of the IRB/IEC approval certificate the notification of ESIMeC must be retained at each institution. The faxed copies will be kept at the iPocc Trial Coordinating Center.

[Japan Only]

14.7 Annual renewal of IRB/IEC Approval

Annual renewal requirements for the protocol and informed consent documents to be reviewed and approved by the IRB/IEC will be in accordance with the applicable regulations at each institution. In general, when any amendments are made to the protocol or informed consent documents during the course of the clinical trial, the amended protocol and informed consent documents must be approved by the IRB/IEC. However, depending on the content of the amendments, the need for such approval can be determined by each institution.

14.8 Changing the content of the protocol

Changes to the protocol made after approval by the IRB/IEC will be handled as two separate items: "Amendments" and "Revisions." In addition, any supplemental explanations without changes to the protocol will be regarded as "Memorandums." The definitions and the handling of these are as follows:

1) Amendment
   A partial change(s) to the protocol that may increase the risk to patients participating in the clinical trial or that affects the primary endpoint in the clinical trial.
   Requires approval by the Clinical Trial Review Committee in JGOG and GOTIC, and must be reported to each IRB in accordance with the policy established by each institution.
   The date of approval by the Clinical Trial Review Committee will be noted on the cover page of the protocol.
2) Revision
   A change(s) to the protocol that is not associated with any increased risk to patients participating in the clinical trial and that is not associated with the primary endpoint in the clinical trial.
   Does not require review by the Clinical Trial Review Committee, but should be reported.
   It is not necessary to record the date of approval by the Clinical Trial Review Committee on the cover page of the protocol.
   The requirement of the IRB/IEC for review and approval will be in accordance with the decisions made by the institution in accordance with their policies.
3) Memorandum
   Not a change(s) to the protocol but a supplemental explanation(s) to be distributed from the study chair to the trial-related personnel in order to reduce the differences in interpretation of the text or to promote awareness. It requires no review by the IRB.

14.9 Conflicts of interest (COI)

With regards to "the conflicts of interest in this clinical trial" of the study chair and investigators at each institution, the self-declaration forms submitted by investigators are reviewed and approved by the COI Review Committee or the IRB/IEC. Moreover, any conflicts of interest of the iPocc Trial Coordinating Center personnel and the statisticians will be reviewed and approved in compliance with the rules established by each organization.

When publishing the results of this clinical trial, the self-declaration forms for "the conflicts of interest in this clinical trial" of all investigators who will be listed as conference presenters and/or authors will be submitted to the COI Review Committee of GOTIC/JGOG for review. The publication of the clinical trial results will not be presented at domestic/international conferences or in medical journals until the conflicts of interest of all presenters/authors are approved by the COI Review Committee of the GOTIC/JGOG.

14.10 Financial support

This clinical trial is conducted with support by the Health Science and Labor Research Grants from the Ministry of Health, Labor and Welfare (MHLW). Some research funds from study groups also partially support this trial. The Gynecologic Oncology Trial and Investigation Consortium of North Kanto (GOTIC) are providing assistance in meeting the costs incurred in supporting the Clinical Research Coordinator (CRC) and the meeting organization. In addition, the cost for on-site monitoring and auditing are supported by the Japanese Gynecologic Oncology Group (JGOG).

Because part of the treatment to be used in this clinical trial involves a dosage and route of administration not covered by public health insurance, the drugs to be used for that portion will be provided by the pharmaceutical companies. Accordingly, treatment consisting of that covered by public health insurance and treatment provided at no cost will be conducted under the advanced medical care evaluation system established by the MHLW.

[Japan Only]

15 MONITORING AND AUDITING

International institutions outside Japan may need to refer to their country specific appendix for MONITORING AND AUDITING.

15.1 Monitoring of the study

Central monitoring will be performed by the iPocc Trial Coordinating Center in order to ensure that the clinical trial is conducted safely and in accordance with the protocol, and that the clinical trial data are accurately collected. On-site monitoring will be performed in accordance with the monitoring plan for the trial separately specified.

Routine monitoring reports, as a general rule, will be prepared twice a year on the basis of the reported data on eCRFs collected by the iPocc Trial Coordinating Center. The routine monitoring reports prepared by iPocc Trial Coordinating Center will be submitted to the Monitoring Committees and the Independent Data Monitoring Committees (IDMC) of both JGOG and GOTIC semi-annually, and international IDMC annually.

15.1.1 Routine monitoring

15.1.1.1 Monitoring procedures

The Committees of JGOG/GOTIC will review the routine monitoring reports.

15.1.1.2 Monitoring items

1) Patient accrual
2) Patient eligibility
3) Background information on patients
4) Status of protocol execution with reasons for discontinuation
5) Adverse events, especially SAE (serious adverse events) and the reporting status of such events
6) Protocol deviations (including cases of a possible deviation) and violations
7) Others, including the issues related to the progress and the safety of the clinical trial

15.1.1.3 Protocol deviations and violations

A protocol deviation occurs when drug administration, laboratory tests, or evaluation of toxicity and efficacy are not performed as specified in the protocol.

Deviations that exceed the scope of certain acceptable deviations previously determined by the iPocc Trial Coordinating Center and the study chair for each clinical trial will be listed on the monitoring reports as "a case with a possible deviation" and classified as one of the following after review by the monitoring committees.

1) Protocol violation

In principle, "a protocol violation" is a deviation from the protocol described below:

① That has an impact on the evaluation of the primary endpoint of the clinical trial

② That is caused by investigators or institutions without consultation with the study chair in advance.

③ That is intentional or systematic
④ That poses a risk or departs from the protocol significantly

Protocol violations will be disclosed upon publication of the study results.

(Examples of violations)

- Giving other types of chemotherapy or excluded concomitant medications during the protocol treatment
- Giving excess overdoses

2) Protocol deviations

A deviation that does not fall under either 1) Protocol violation or 3) Acceptable deviation.
A specific deviation observed in many cases may be stated when publishing the study results.

3) Acceptable deviation

A deviation within the scope of the acceptable deviations from the protocol previously or subsequently established by the iPocc Trial Coordinating Center and the study chair for each clinical trial.
They will not appear on the monitoring reports.

15.1.1.4 Review by the Independent Data Monitoring Committee (IDMC)

An IDMC will meet semi-annually to assess the progress of the clinical trial and the safety (and efficacy data for interim analysis) during the course of the clinical trial with the aim of recommending whether to continue, modify, or stop the clinical trial.

When the results from the phase A trial are available, the IDMC will review this data and decide whether to continue or discontinue the clinical trial. A decision to continue or discontinue the clinical trial will be made in a comprehensive manner that includes a review of the feasibility, together with possible efficacy, and on the basis of the result of the review, the IDMC will make a recommendation to the study chair regarding whether to continue or stop the clinical trial. If a decision is made to continue the clinical trial, the efficacy data in phase A will not be published. If it is decided to stop the clinical trial, all the data will be published.

An international IDMC will conduct the same review as described above on an annual basis. The international IDMC will operate in accordance with the following guidelines.

- The membership of the IDMC will include at least one inter-group statistician and at least one clinician experienced in clinical trials. Additional membership will reflect the specialties involved in the trial. All members of the IDMC will be independent of the trial. If non-independent members are to be included this will be justified and agreed to by the participating GCIG groups.
- The deliberations of the IDMC when considering outcome data by treatment arm are confidential. These data will not to be shared with anyone who is not a member of the IDMC, unless agreed by the IDMC itself.
- The IDMC will act in an advisory role and report its recommendations in writing to the study chair.
- A recognized formal statistical approach for the conduct of interim analyses will be employed and in general the final recommendation from the IDMC on the continuation of the study will

be based on all available evidence. The formal statistical criteria for stopping on basis of efficacy in this study are described in section 13. STATISTICAL ANALYSIS.

- The IDMC must formally approve any proposed publication of any trial data prior to the publication of the protocol-specified definitive analysis based on the primary endpoint.

15.2 Audit

For JGOG institutions, this study is the subject of an audit by the JGOG/GTOIC Audit Committees. Auditors appointed by the audit committee will visit the participating institutions, and verify the essential documents such as IRB/IEC approval and signed consent form. The auditors also verify the accuracy of the reported data in the eCRFs against original medical records as necessary in accordance with the procedures specified by the GOTIC/JGOG.

The audit results of each institution will be reported only to the investigator at the institution concerned and the GOTIC/JGOG audit committees. If published to any third party, the name of the institution will not be disclosed.

16 SPECIAL INSTRUCTIONS

16.1 Central evaluation of tumor response

In this study, central evaluation of tumor response will not be performed.

16.2 Central pathology review

A Central Pathology Review Committee will be convened once a year to review up to three representative slides per patient. These prepared slides will be reviewed to confirm if the pathological diagnosis is being properly conducted and to ensure that eligibility criteria are being met. The review may be performed using a web-based imaging system. The Central Pathology Review Committee for this trial will consist of the members of the GOTIC/JGOG Central Pathology Committee, as well as pathologists who belong to other study groups. As a general rule, prepared slides reviewed by the Central Pathology Committee will not be returned.

17 STUDY REGISTRATION AND PUBLICATION OF FINDINGS

This clinical trial will be registered through the University hospital Medical Information Network Clinical Trials Registry (UMIN-CTR) in Japanese with the URL http://www.umin.ac.jp/ctr/index-j.htm, and clinical.gov in English with the URL http://clinicaltrials.gov/ to disclose information regarding the design, conduct, and publication of results of the clinical trial.

The study results will be presented at a medical meeting after the completion of the final analysis and published in an appropriate medical journal.

17.1 Publication of the results of the phase A trial

At the completion of the data analysis of the phase A trial, data other than the efficacy data will be presented at a medical meeting and the results will be published in an appropriate medical journal. However, if the clinical trial is discontinued, all results including the efficacy results will be published.

17.2 Guidelines on authorship of research papers

Authorship of research papers will be as follows: The first and second authors of the research paper will be either the study chair or the investigator/sub-investigator who belongs to the institution with the highest number of registered subjects. The selection of the first author at such an institution will be determined by the institution. However, the first author should be the person who most directly contributed to this clinical trial.

If the representative at such an institution with the highest number of registered subjects declines to be the first author, the study chair will be the first author and the representative at the institution with the highest number of registered subjects will be the second author.

The third and other authors will be determined through consultation among the participating investigators/ sub-investigators with high accrual. Other authors can include the international study co-chairs, a statistician, and/or appropriate representative from the iPocc Trial Coordinating Center. Since this is an international co-operative trial, the international study co-chairs who are actively involved will be included as authors.

18 RESEARCH ORGANIZATION

This is a Gynecologic Cancer Intergroup (GCIG) study.

18.1 Study chair

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18.4 iPocc Trial Coordinating Center

(Project management, data management)

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18.6 Research support organization 【See Attachment 1】

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Ⅲ. 高度医療承認書

関厚発１１３０第７３号
平成２２年１１月３０日

下野市薬師寺３３１１－１

学校法人自治医科大学
自治医科大学附属病院
学校法人自治医科大学
香山　充弘　様

関東信越厚生局長

先進医療の届出の受理について（通知）

さきに届出のありましたこのことについて、下記のとおり受理したので通知します。

記

受理番号	（先１７７）第１号
受付年月日	平成２２年１１月３０日
算定開始年月日	平成２２年１２月　１日

関厚新発１１３０第 ６号
平成２２年１１月３０日

新潟市中央区川岸町２丁目１５番地３

新潟県立がんセンター新潟病院
新潟県病院事業管理者
新潟県病院局長 江口 孝雄 殿

関東信越厚生局新潟事務所長

先進医療の届出の受理について（通知）

さきに届出のありましたこのことについて、下記のとおり受理したので通知します。

記

１ 受理番号	（先１７７）第２号
２ 受付年月日	〃
３ 算定開始年月日	平成２２年１２月１日
４ 該当先進医療	パクリタキセル静脈内投与（一週間に一回投与するものに限る。）及びカルボプラチン腹腔内投与（三週間に一回投与するものに限る。）の併用療法 上皮性卵巣がん、卵管がん又は原発性腹膜がん

東北厚発１１３０第５４号
平成２２年１１月３０日

東北大学病院
開　設　者　殿

東北厚生局長

先進医療の届出の受理について（通知）

さきに届出のありましたこのことについて、下記のとおり受理したので通知します。

記

1　受理番号
（先１７７）第１号
2　受付年月日
平成２２年１１月３０日
3　算定開始年月日
平成２２年１２月　１日
4　該当先進医療
パクリタキセル静脈内投与（一週間に一回投与するものに限る。）及びカルボプラチン腹腔内投与（三週間に一回投与するものに限る。）の併用療法　上皮性卵巣がん、卵管がん又は原発性腹膜がん

院長	副院長	統括診療部長	臨床研究部長	事務部長	看護部長	薬剤部長	企画課長	経営企画室長	班長	係長	係

四厚受第１１３０第９号
平成２２年１１月３０日

独立行政法人国立病院機構四国がんセンター

開　　設　　者殿

四国厚生支局長

先進医療の届出の受理について（通知）

さきに届出のありましたこのことについて、下記のとおり受理したので通知します。

記

受　理　番　号	（先１７７）第１号
算定開始年月日	平成２２年１２月　１日
該当先進医療	パクリタキセル静脈内投与（一週間に一回投与するものに限る。）及びカルボプラチン腹腔内投与（三週間に一回投与するものに限る。）の併用療法　上皮性卵巣がん、卵管がん又は原発性腹膜がん

独立行政法人
国立病院機構
四国がんセンター
22.12.16

中厚発1130第43号
平成２２年１１月３０日

鳥取市立病院
鳥取市長　竹内　功　　殿

中国四国厚生局長

既に第３項先進医療として先進医療告示に定められている
医療技術に係る届出の受理について

標記について、下記のとおり受理しましたので通知します。
なお、保険医療機関及び保険医療養担当規則に基づき、院内掲示を行って下さい。

記

1　届出事項

先進医療の新規届
技術名：パクリタキセル静脈内投与（一週間に一回投与するものに限る。）及びカルボプラチン腹腔内投与（三週間に一回投与するものに限る。）の併用療法
上皮性卵巣がん、卵管がん又は原発性腹膜がん

2　受理番号

（先１７７）第１号

3　算定開始年月日

平成２２年１２月１日

受付 891号
22.12.10
鳥取市立病院

関厚発０１３１第１０１号
平成２３年 １月３１日

宇都宮市陽南４－９－１３

栃木県立がんセンター
福田 富一 様

関東信越厚生局長

先進医療の届出の受理について（通知）

さきに届出のありましたこのことについて、下記のとおり受理したので通知します。

記

受理番号	（先１７７）第２号
受付年月日	平成２３年 １月２８日
算定開始年月日	平成２３年 ２月 １日