Introduction/Background Standard of care chemotherapy in patients (pts) with advanced ovarian cancer (AOC) is the combination of carboplatin and paclitaxel (C/P). Data from the PRIMA trial has shown a significant benefit in pts by the addition of a maintenance treatment (MT) with niraparib irrespective of BRCA or HRD-status in high-grade AOC. The PAOLA-1 trial evaluated MT in pts with AOC with the combination of olaparib and bevacizumab and has also shown a significant benefit compared to bevacizumab monotherapy. However, the role/benefit of bevacizumab in addition to PARP-inhibitor (PARPi) in MT is unclear. Therefore, we investigate, if the treatment strategy of carboplatin/paclitaxel/bevacizumab/PARPi is superior to the treatment of carboplatin/paclitaxel/PARPi in a population regardless of biomarker status.

Methodology AGO-OVAR 28/ENGOT-ov57 (NCT05009082; EudraCT-Number: 2021–001271–16) is a multicenter, randomized, prospective phase III trial. The trial population is composed of adult pts with newly diagnosed, high-grade epithelial AOC, primary peritoneal cancer or fallopian tube cancer FIGO III/IV (except FIGO IIIA2 without nodal involvement). All pts should have completed cycle1 of chemotherapy (C/P) as part of Study-Run-In-Period. Prior to cycle1 of cycle2, pts with a valid central tumor BRCA (tBRCA) test result will be randomized 1:1 into either Arm1 and will receive 5 additional cycles of C/P q21d followed by niraparib for up to 3 years; or into Arm2 where pts will receive 5 additional cycles of C/P plus bevacizumab q21d followed by bevacizumab q21d (for up to 1 year) and niraparib for up to 3 years. Patients who are scheduled for neoadjuvant chemotherapy and interval debulking surgery can also be enrolled. The primary objective is progression-free-survival (PFS). Secondary objectives include but are not limited to: PFS according to tBRCA-status, overall survival, PFS2, safety/tolerability, and quality of life. First-Patient-First-Visit is expected in August 2022. Target recruitment is 970 patients.

Results Trial-In-Progress.

Conclusion Trial-In-Progress.

Introduction/Background Comprehensive identification of ovarian cancer (OvCa) patients that can benefit from poly (ADP-ribose) polymerase inhibitors (PARPi) treatment is currently based on genome-wide enumeration of known Homologous Recombination Deficiency (HRD) biomarkers and requires deep sequence profiles (>30x). The cost and challenges of implementing available solutions currently hinders clinical adoption of HRD testing. We present the interim results for the ongoing multicenter evaluation study of SOPHIA DDM Dx HRD (SOPHIA GENETICS, SA), a novel deep learning-based solution that leverages the impact of HRD on the coverage profiles from low-pass whole-genome sequencing (lpWGS, 1x) data.

Methodology In this multicenter study, we processed and analyzed according to manufacturer’s instructions, DNA from 319 formalin-fixed paraffin-embedded (FFPE) OvCa samples. We assessed the concordance between SOPHIA DDM Dx HRD solution and Myriad myChoice® CDx results. For the subset of our cohort (206 samples) included in the PAOLA-1 clinical trial, we carried out survival analysis to investigate differences in progression-free survival (PFS) in the olaparib and placebo arms of the study between patients, with HRD positive or non-positive tumors.

Results We found a high overall percentage agreement, 90.48% (95% confidence interval [CI], 86.58–93.33), between SOPHIA DDM Dx HRD and Myriad myChoice® CDx status. The median PFS time for patients with HRD positive tumors was 20.8 months higher in the olaparib arm (hazard ratio [HR], 0.44; 95% CI, 0.26–0.76, P=0.003). No significant
difference in PFS was observed between treatment arm in patients without HRD positive tumors (HR, 0.92; 95% CI, 0.59–1.43; P=0.69). The effect of the interaction between olaparib and HRD status on PFS, in the interim study, was similar for the two stratification methods (P=0.20).

Conclusion The interim results of SOPHiA DDM Dx HRD Solution evaluation study support the value of IgWGS data for patient stratification, making it suitable for HRD testing in the clinical setting.

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A PILOT STUDY OF INTERVAL CYTOREDUCTIVE SURGERY AND HIPEC FOR ADVANCED EPITHELIAL OVARIAN CANCER IN THE UK

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Introduction/Background The Christie is one of the first cancer referral centres to offer hyperthermic intraperitoneal chemotherapy (HIPEC) to patients with advanced epithelial ovarian cancer (AEOC) in the UK. Despite the OVIHIPEC trial showing longer recurrence-free and overall survival for patients undergoing interval cisplatin cytoreductive surgery (CRS) with the addition of HIPEC compared to CRS alone, HIPEC is not yet offered as NHS-funded treatment for AEOC. We report early follow-up data on safety and feasibility of CRS+HIPEC in ovarian cancer patient at the Christie, including costs, adding to the evidence that HIPEC is a cost-efficient addition to current treatment for patients with AEOC.

Methodology Patients with high grade AEOC who achieved a partial response to 3 or 4 cycles of neoadjuvant carboplatin and paclitaxel chemotherapy were selected for interval CRS+HIPEC. The procedure was performed by Gynaecological Surgical Oncologists in collaboration with Peritoneal Surgeons with extensive experience in performing HIPEC procedures. Closed HIPEC delivery technique was used. Cisplatin was perfused at a dose of 100 mg/m2.

Results 9 patients have undergone CRS+HIPEC for AEOC at The Christie since October 2021. By the LBA submission deadline, this will be 10. We will report on median time to surgery from chemotherapy, pre- and postsurgical PCI score, mean length of stay and CCU stay, intra- and postoperative complications and 30 and 90 day mortality. Overall costs of the postoperative care of CRS+HIPEC will be compared to CRS alone in our setting.

Conclusion Interval CRS+HIPEC is feasible and safe for AEOC in a tertiary cancer centre setting. There does not seem to be a significant difference in postoperative complication rate and associated costs compared to the current standard treatment of interval CRS alone.

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SYSTEMATIC NURSE-LED CONSULTATIONS BASED ON ELECTRONIC PATIENT-REPORTED OUTCOMES AMONG WOMEN WITH GYNAECOLOGICAL CANCER DURING CHEMOTHERAPY-THE CONNECT STUDY

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Introduction/Background During chemotherapy, women with ovarian and endometrial cancer experience a significant physical and psychological burden due to the disease and treatment. Patient-reported outcomes (PRO) can help enhance patient-clinician communication, symptom management, patient satisfaction, and quality of life (HRQoL), and electronic PRO (ePRO) can provide appropriate and continuous symptom monitoring. The objective of this study is to develop and investigate the feasibility and effect of systematic nurse-led consultations based on ePRO integrated into a multidisciplinary treatment regimen for patients with ovarian- and endometrial cancer on HRQoL.

Methodology A quasi-experimental four-phase, sequential cohort research design with comparisons between non-equivalent groups. This study will examine: 1) the frequency and severity of clinician-reported symptoms and adverse events, HRQoL (EORTC QLQ-C30+ OV-28/EN-24), levels of anxiety and depressive symptoms (HADS), and self-efficacy (SES6G) among women with ovarian- or endometrial cancer receiving standard care (n=41), 2) developmental phase, 3) test the feasibility of systematic nurse-led consultations based on ePRO (n=20), 4) estimate the effect of the ePRO based model on frequency and severity of nurse-reported symptoms and adverse events, HRQoL, HADS, and SES6G compared to standard care (n=41). The difference in global HRQoL (EORTC QLQ-C30) after 9 months will be the primary outcome. Further, we will conduct qualitative individual and focus-group interviews to explore experiences and satisfaction among patients, nurses, and physicians.

Results We will involve a patient advisory board throughout the research phases to provide research feedback, comment on written materials, and contribute to the research’s progress. In addition, the algorithms on the ePRO platform separate the patient’s response to symptom severity into three levels.

Conclusion We hypothesize that proactive use of ePRO in nurse-led consultations may contribute to increased quality of life, symptom- and self-management, and CONNECTion between patients and healthcare professionals.