ESMO in Madrid, Spain, 20 – 24 October 2023

This year the huge ESMO (European Society of Medical Oncology) was held at the IFMA Congress Centre in Madrid. There were about 33.000 participant and there were sessions about all types of cancer. There was also a patient advocacy track.

I followed almost all sessions in the patient advocacy track, but also all sessions in relations to gynaecological cancer that I was able to follow within the timeframe.

I have attended ESMO before and also attended ESMO at IFEMA in Madrid in 2016.

Below is my account of some of the many sessions of interest

By Birthe Lemley

Frontiers in Gynaecological Cancer – Roundtable – GSK – 19 October 2023

I was invited to a roundtable discussion by the pharmaceutical company GSK together with other patient advocates from ENGAGe. There were presentations by some of the people working very closely with GSK on this topic. Among them was the chief executive officer of the World Ovarian Coalition Clara MacKay, whom I have met on other occasions. I was present when we decided to make the 8 May a World Ovarian Cancer Day in 2017. This initiative came from Canada and Clara MacKay is Canadian.

Director of Patient Engagement Bonnie Pobiner from GSK was leading the meeting. She is sitting to the right behind the computers. Clare McKay is the third person in the panelist from the right and the representative from New York is sitting to the left of her. As you will see there were also representatives on the big screen.

The discussion dealt with helping all women with gynaecologcal cancer - mostly to manage in the sometimes very difficult systems in the various countries. The representative from New York talked about how they were helping women with no healthcare insurance. This is a problem in many countries – but fortunately not in Denmark.

I talked about Shared Decision-making in Denmark and explained that when the doctor and the patient have to agree on a new treatment, it is done by pictograms so that everybody can understand it. It can for instance be used to show the various side effects of the treatment. I also mentioned that some women tell

the oncologist that he/she should make the decision, but that is also a decision made by the patient. I also talked briefly about the Clinical Trials Project that GSK supports with funding, but they are not using us, which I also mentioned.

There were many good discussions among the women both from ENGAGe (Petra Adamkova, Co-chair of ESGO ENGAGe, Coralie Marjollet, President of IMAGYN, France and me), and the invited speakers. The representatives from GSK – who were also women that I have met before – have promised to come back to us in view of the many important issues discussed.

After the meeting in Madrid, I have received a statement from them with the photos and comments below. We will meet with GSK at the ENGAGe PAS in Barcelona from 6 – 10 March 2024 and will have a chance to talk to some of them again.

Below is excerpts from the e-mail received:

Thank you again for joining our Frontiers in Gynaecological Cancer (FGC) Roundtable on 19 OCT. We are happy to share the attached summary of what was discussed, including featured initiatives that align with the community-driven prioritised ***goals and strategies to improve inequities in gynaecological cancer care for marginalised individuals in high income countries.***

Our next steps will be to establish a communication plan to keep you and others in the gynaecological cancer community informed as the program moves forward in 2024. We will share more details as we work towards actionable solutions to benefit individuals facing a gynaecological cancer diagnosis.

Warm regards,

Clara MacKay

Clara MacKay
CEO, World Ovarian Cancer Coalition
WORLD OVARIAN CANCER COALITION
NO WOMAN LEFT BEHIND

Bonnie Pobiner

GSK
Bonnie Pobiner, PhD
Director, Patient Engagement
Global Oncology, Patient Focused Development

THANK YOU!

- ***Thank you for supporting the Frontiers in Gynaecological Cancer (FGC) Initiative*** and for your active participation in the 2023 FGC Roundtable on 19 October in Madrid.
- This report summarises the activities, discussion and outcome of the 2023 FGC meeting.

GSK

Thank you for supporting the Frontiers in Gynaecological Cancer (FGC) Initiative and for your active participation in the 2023 FGC Roundtable on 19 October in Madrid.

This report summarises the activities, discussion and outcome of the 2023 FGC meeting.

The report is attached.

Meeting Overview

Thursday 19 October 2023 | Santo Domingo Hotel, Madrid, Spain | 5:00 – 8:15 PM

Participants

44 participants
- **13** in person
- **23** online
- **8** panelists

21 patient advocates and organizations

14 countries

Canada • Czech Republic • Denmark • Finland • Germany • Ireland • Israel • Italy • Netherlands • Portugal • Spain • Switzerland • UK • USA

GSK

The next meeting I attended on behalf of ENGAGe is described below:

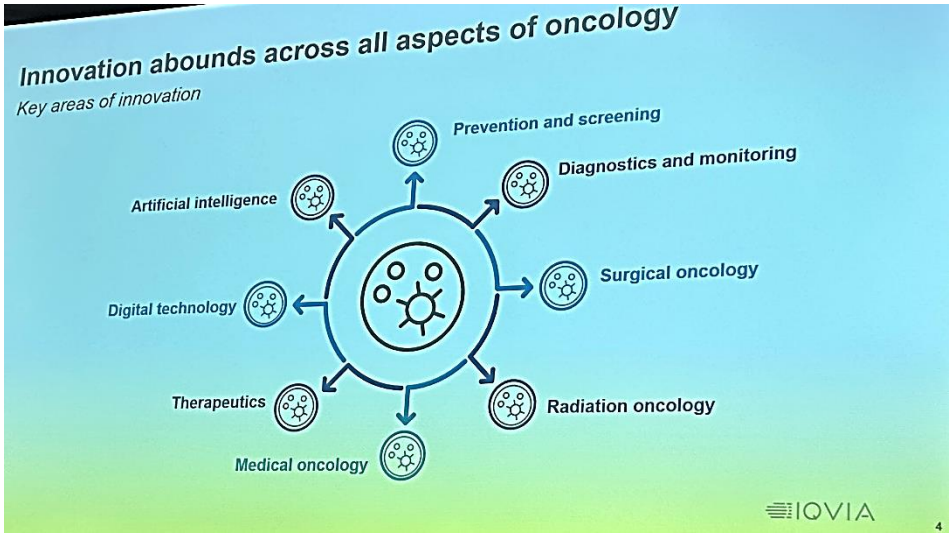
IQVIA - Institute Accelerating the Impact of the Cancer Mission Five-fold: How and where should Europe Invest to improve Cancer outcomes in 10 Years instead of 50 Years – 20 October 2023

What is IQVIA? I found this statement on their webpage

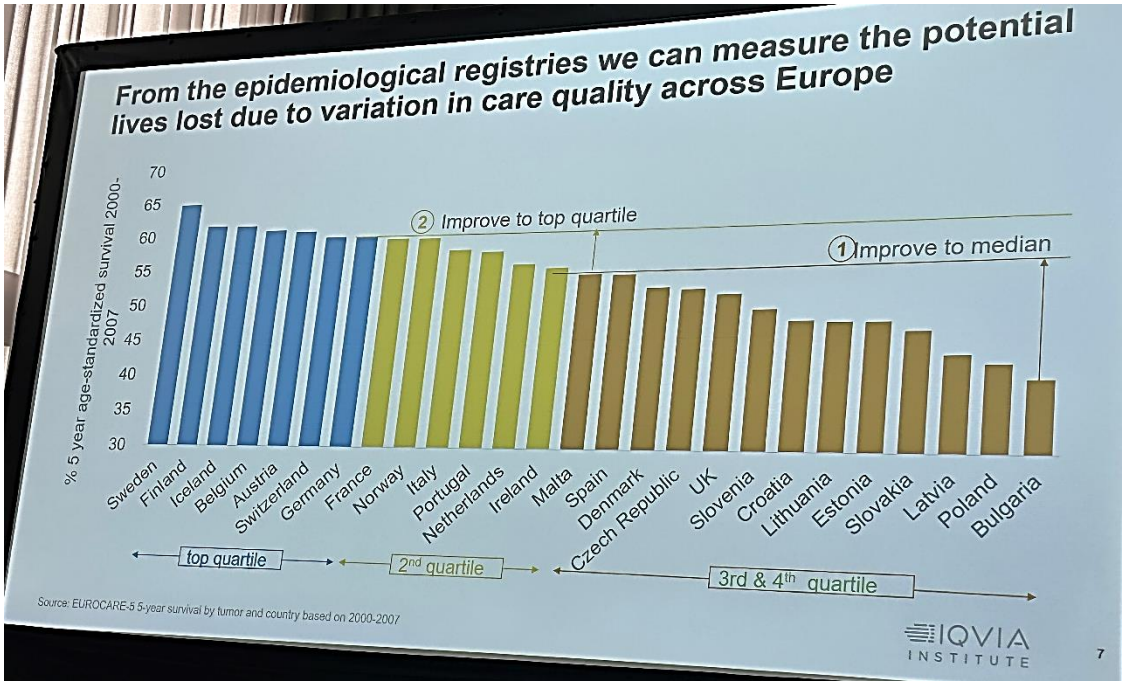
At IQVIA, we are passionate about helping customers and partners improve results and patient outcomes. Everything we do contributes to this vision for creating a healthier world.

This was an extremely interesting session, and I actually knew two of the presenters. They were Ane Appelt, who was present at the ESGO ENGAGe meeting in Berlin teaching the clinical trials group about clinical trials, and Kristina Lindemann, who was a presenter at one of the webinars in the Clinical Trials Project, and who was also present at the recent ENGOT meeting in Leuven in Belgium. In Belgium she asked me to write a letter of support on behalf of ENGAGe for a trial that she wanted to start. This has been done. The trial was about deescalating treatment of a certain FIGO type of endometrial cancer, i.e., POLE-mut. Some patients, whose endometrial cancer is FIGO type POLE-mute, will never have a relapse and therefore don't need any kind of treatment. This is extremely important to the patient but not necessarily to the pharma industry. Therefore, it is difficult to obtain funding for such a trial.

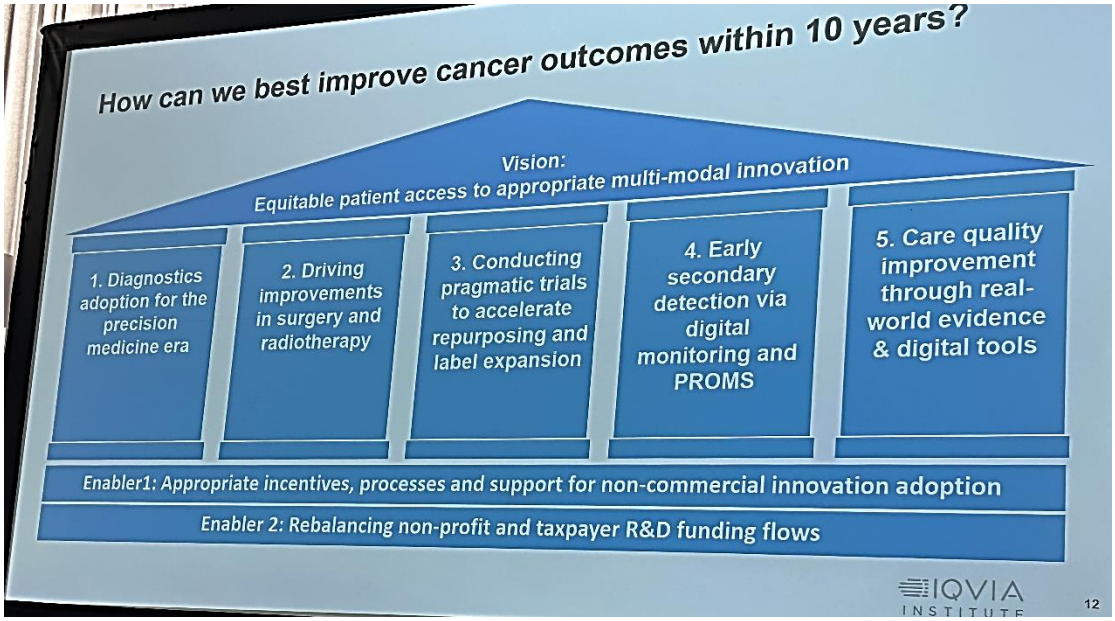
It is Ane Appelt and Kristina Lindemand to the right in the picture. All speakers were excellent. I was impressed.
From the left they are Kate Roges, CEO. Follicular Lymphoma Foundation, Piers Mahon, Senior Principal, Digicore and IQVIA, Peter Lindgren, Managing Director, The Swedish Institute for Health Economics, Shirin Ahmed, Head of Medical Strategy, Astra Zeneca, Jesus Garcia-Foncillas, Director, Department of Oncology, Universidad Autónoma de Madrid, Nicola Normanno, Director, Cell Biology and Biotherapy Unit, Fondazione Pascale, Ane Appelt, Associate Professor, University of Leeds, Kristina Lindemann, Senior Consultant, Gynaecology and Oncology, Oslo University Hospital, Mark Lawler, Associate Pro-Vice-Chancellor and Professor of Digital Health, Queen's University Belfast



Above are the areas being discussed.



Variation in quality care across Europe – what a difference among the European countries! Denmark is in 'Improve to median' and Sweden is at the top!



The above is IQVIA's vision. It is a very ambitious plan for the next 10 years. Let us hope they succeed. You can read more about IQVIA here: [About - IQVIA]

ESMO (European Society of Medical Oncology) 2023 was held from 20 – 24 October at the IFMA Congress Centre in Madrid

The patient advocates' sessions were held in the Cadiz Auditorium in Hall 10

On the first day we listened to the Caregiver Perspective and How to get Access to Medicine? These two sessions were for patient advocates

At 18.00 hours all patient advocates were invited to Apéro*. This event was in the area outside the Cadiz auditorium where we also had lunch every day. We, who knew each other from ENGAGe, had previously agreed to meet there, which we did. A lot of patient advocates turned up and chatted with each other.

*Apéro from the French word Aperitif is a get-together, usually featuring drinks such as wine and beer, fruit juices with some light food served before a meal

Below is a picture of some of us from ENGAGe.

They are Charo Hierro from ASACO, Spain, Petra Adámkova co-chair at ESGO ENGAGE, Carolie Marjollet, IMAGYN, France, and Birthe Lemley, KIU, Denmark. Maria Papageorgiou from Greece, Bar Levy and Vanka from Israel, and Eva-Maria Strömsholm from Finland were also attending ESMO.

Below follow minutes from some of the exiting sessions that I listened to:

Ovarian Cancer – first-line sponsored by GSK

There was talk about Kelim, which stands for chemosensitivity. Kelim should be noted for each patient. If the patient is a low risk patient, there is no benefit from bevacizumab. If there is ascites, bevacizumab should be added as bev. works well in ascites. Bev. does not work in stages I, II and III. If the patient is in stage IV, with no ascites, bev. should still be given. Also, after NACT (Neoadjuvant chemotherapy) and residual tumor and after PARP.

CRF score (CRF measures how well your body takes in oxygen and delivers it to your muscles and organs during prolonged periods of exercise). Generally, the higher your CRF level, the lower your risk for developing a variety of conditions. PARP should be used from the beginning – front-line and bev. preserved for future lines.

Isabelle Ray Cocquard

At the ESMO Congress 2023 (Madrid, 20–24 October), Prof. Isabelle Ray-Coquard from the Centre Leon Bérard, Université Claude Bernard, Lyon, and president of the GINECO group, France, receives the ESMO Award 2023 for her outstanding work in rare gynaecological cancers.

Antonio Gonzalez-Martin, MD, co-director, Department of Medical Oncology, Clinica Universidad de Navarra Prof.

Systemic treatment in ovarian cancer:

ESMO guidelines from 2011 mentioned bevacizumab. ESMO guidelines from 2011 mentioned PARP in the frontline setting. What to do in the relapse setting? Very few patients are refractory to platinum treatment in first-line. If the patient is platinum sensitive in second line, PARP can be given. If bev. in first line, then PARP after carboplatin + PLD (pegylated liposomal doxorubicin).

Cervical Cancer

Prof. Ana Oaknin of the Medical Oncology Service, Vall d'Hebron Institute of Oncology, Vall d'Hebron Barcelona Hospital Campus in Barcelona

Primary results of the BEATcc trial (ENGOT-Cx10/GEICO 68-C/JGOG1084/GOG-3030), a randomised phase III trial of first line atezolizumab (atezo) combined with a platinum doublet and bevacizumab (bev) for metastatic (stage IVB), persistent or recurrent cervical cancer (R/M CC)

Atezolizumab combined with platinum-based chemotherapy and maintenance niraparib for recurrent cervical cancer with a platinum-free interval > 6 months:

In the investigator-initiated phase III BEATcc study, the investigators for the first time evaluated the addition of a PD-L1 inhibitor, atezolizumab, to the standard of care bevacizumab plus chemotherapy regimen established previously in the GOG240 study for metastatic, persistent, or recurrent cervical cancer. The BEATcc study met both of its dual primary endpoints, showing significant and clinically meaningful improvements in both progression-free survival (PFS) and overall survival (OS) in the group with atezolizumab added to first-line standard regimen.

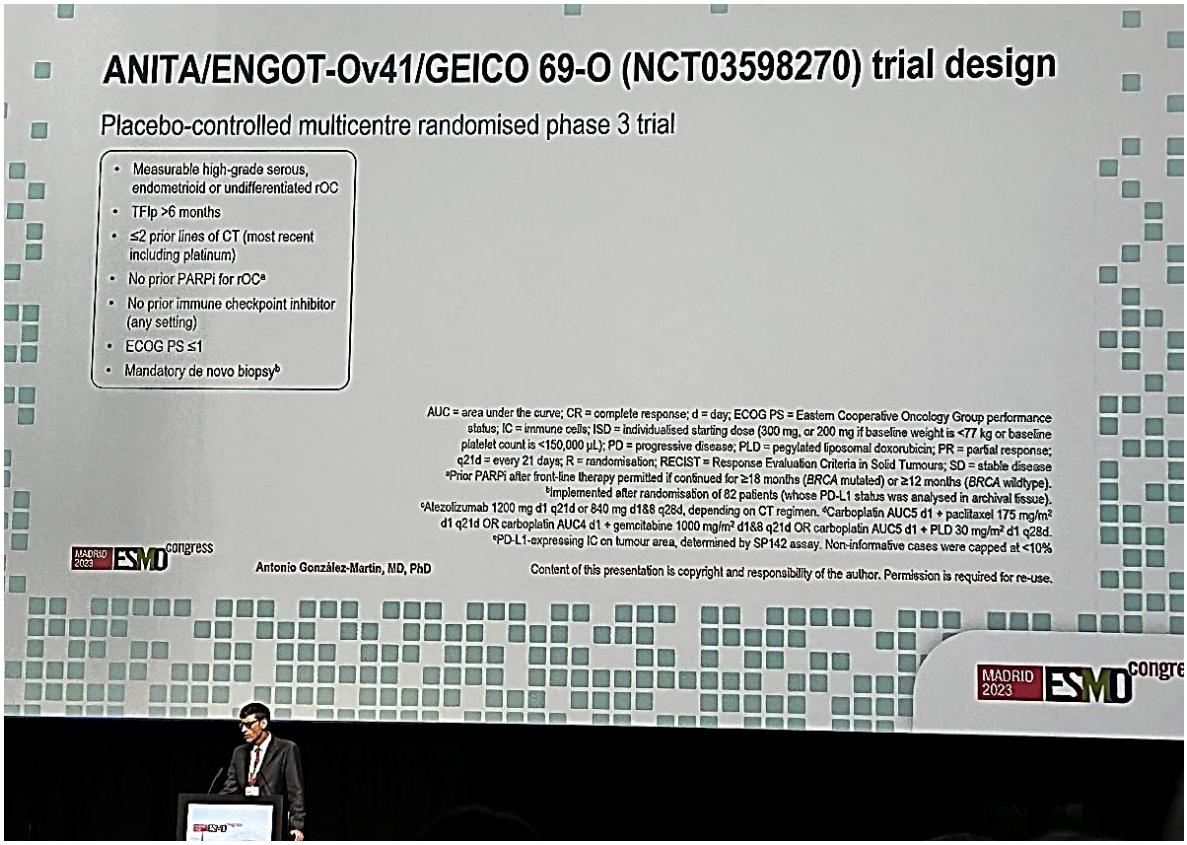
The threshold for significance was met at the interim OS analysis, with an increase in median OS of almost 10 months. Median OS exceeding 2.5 years, with 61% of patients alive at 2 years, represents the current benchmark for first-line treatment of advanced cervical cancer according to Prof. Ana Oaknin of the Medical Oncology Service, Vall d'Hebron Institute of Oncology, Vall d'Hebron Barcelona Hospital Campus in Barcelona, Spain, and colleagues, who published the findings on 1 December 2023 in *The Lancet*.

Patients diagnosed with metastatic, recurrent, or persistent cervical cancer not amenable to local control require systemic treatment and have a poor prognosis. Median OS in GOG240 study was less than 17 months, although this phase III study combining bevacizumab with standard chemotherapy was the first one since studies of platinum agents to show significantly improved OS in this setting. In the subsequent phase III KEYNOTE-826 study, addition of pembrolizumab to first-line chemotherapy with or without bevacizumab significantly improved OS with a median of 26 months.

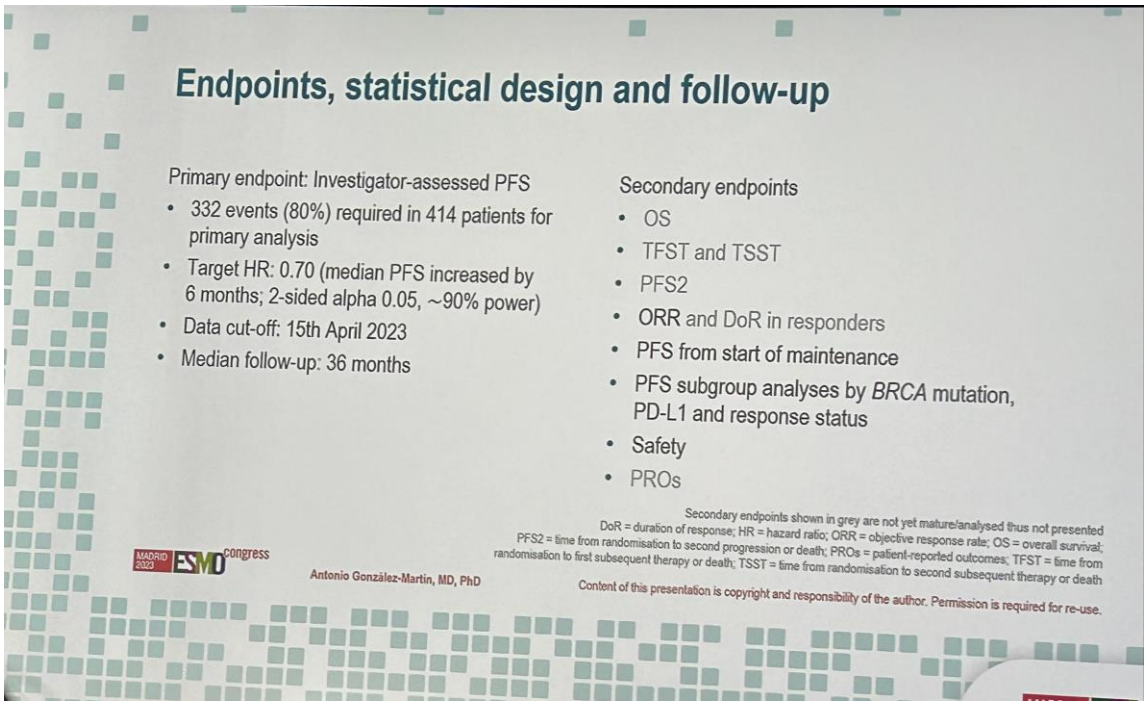
The authors explained that both VEGF and PD-L1 play a role in cervical cancer pathogenesis. Angiogenesis and immune suppression are two facets of a linked biological programme; given the intimate relationship between angiogenesis and immunosuppression, inhibiting both pathways might potentially result in an improved and more durable clinical benefit. The BEATcc study was designed to establish whether combining atezolizumab with bevacizumab plus chemotherapy improves efficacy in the setting of metastatic, persistent, or recurrent cervical cancer.

Primary analysis of the double-blind placebo controlled ENGOT-OV41/GEICO 69-O/ANITA phase 3 trial

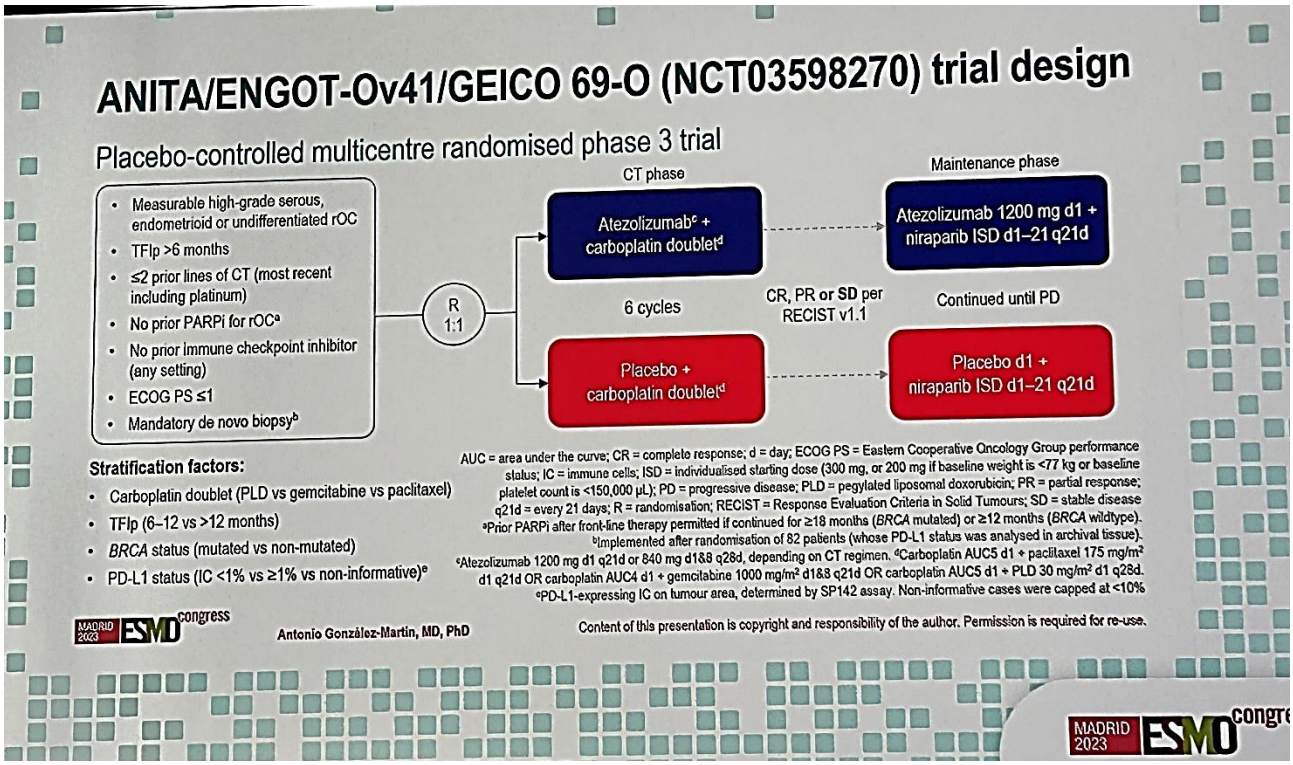
Antonio González Martin, MD, PhD, Cancer Center Clinica Universidad de Navarra, Madrid, Spain



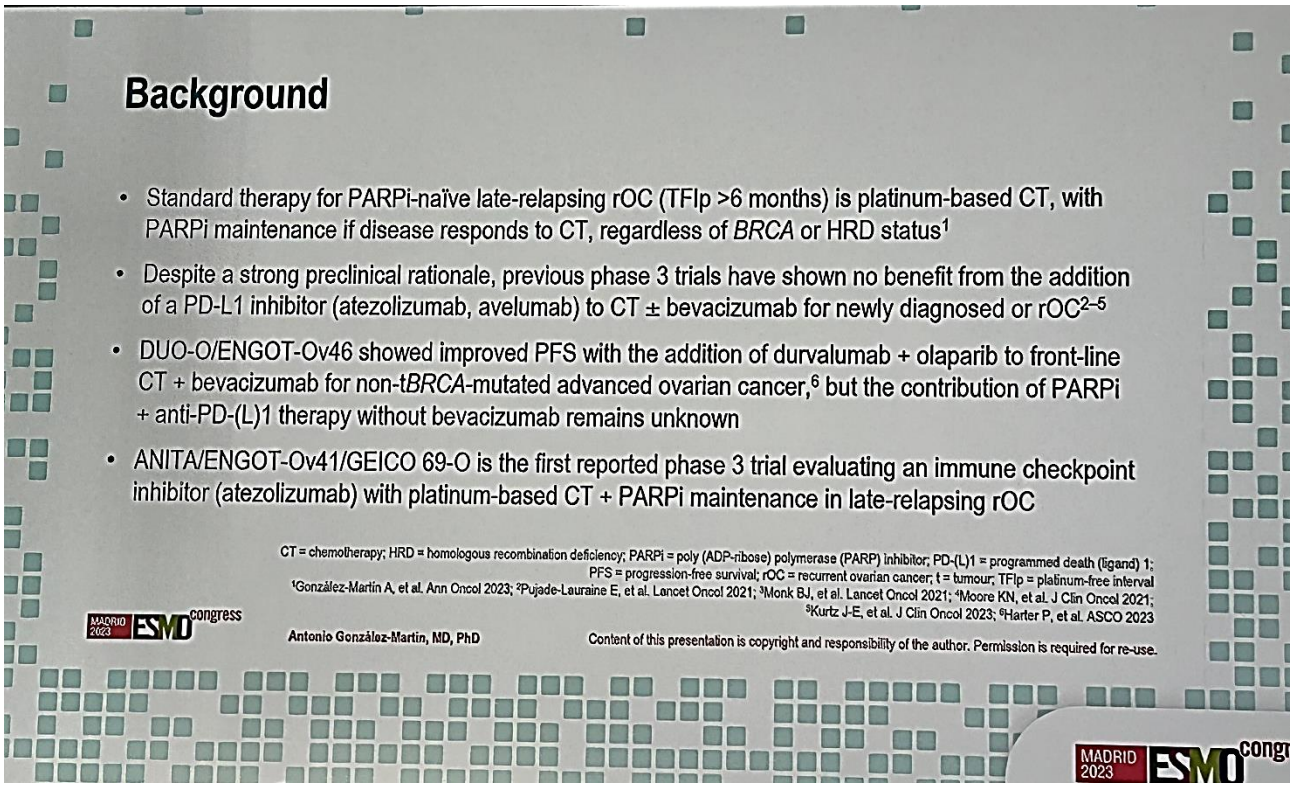
On the slide above you can see the eligibility criteria for entering the study. rOC stands for Recurrent Ovarian Cancer



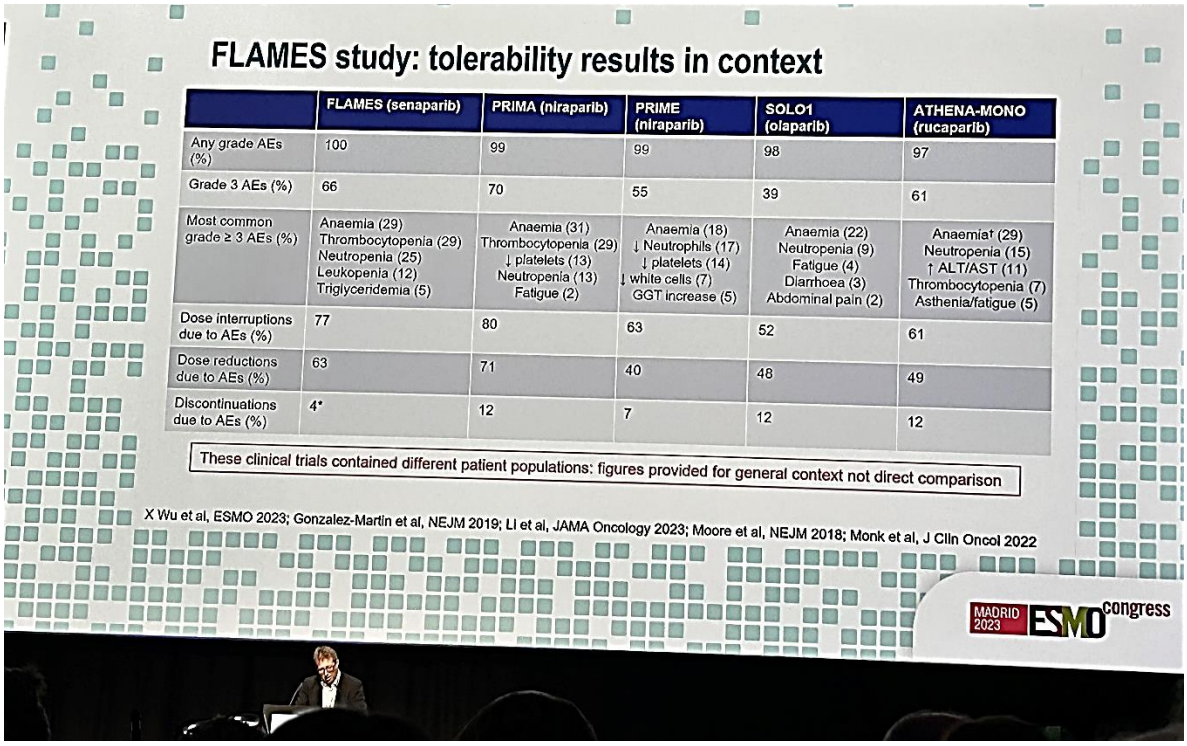
Here is the primary endpoint and the secondary endpoints of the study which is investigator-assessed PFS (progression-free survival). The target HR (Hazard Ratio) is 0.70, which means a reduction in risk of death of 30 %.



In the slide above you see the two arms of the study and the eligibility criteria once more.



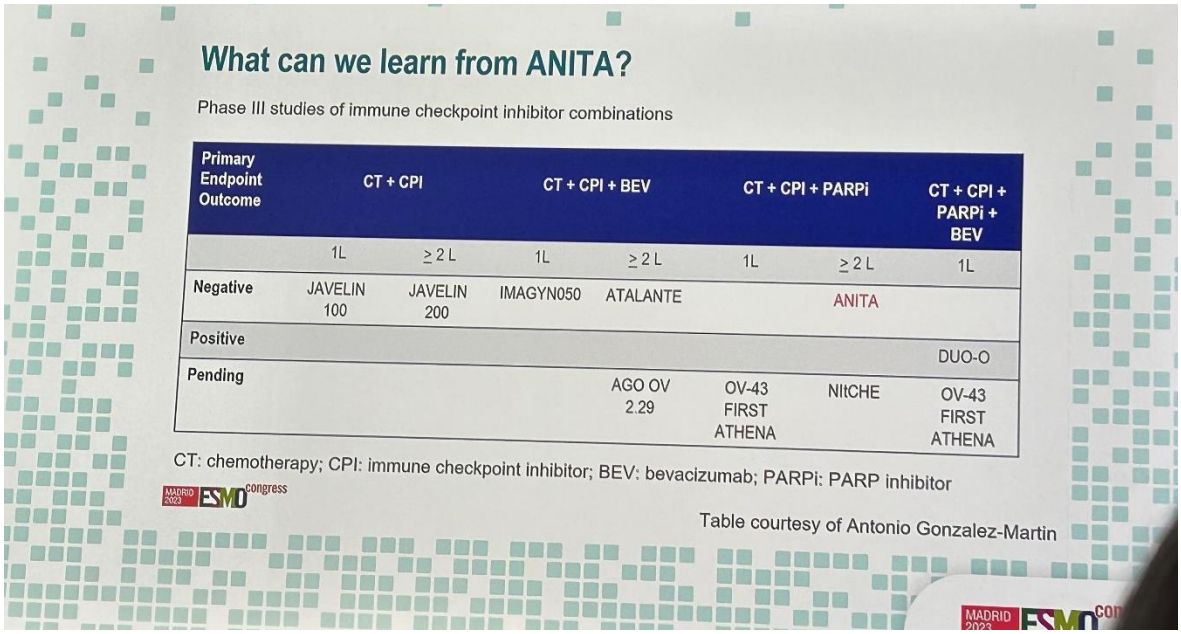
Unfortunately, the ANITA trial turned to be a negative trial. There was no benefit by adding PDL1. Did not really improve OS, but there were side effects. This was a negative trial.



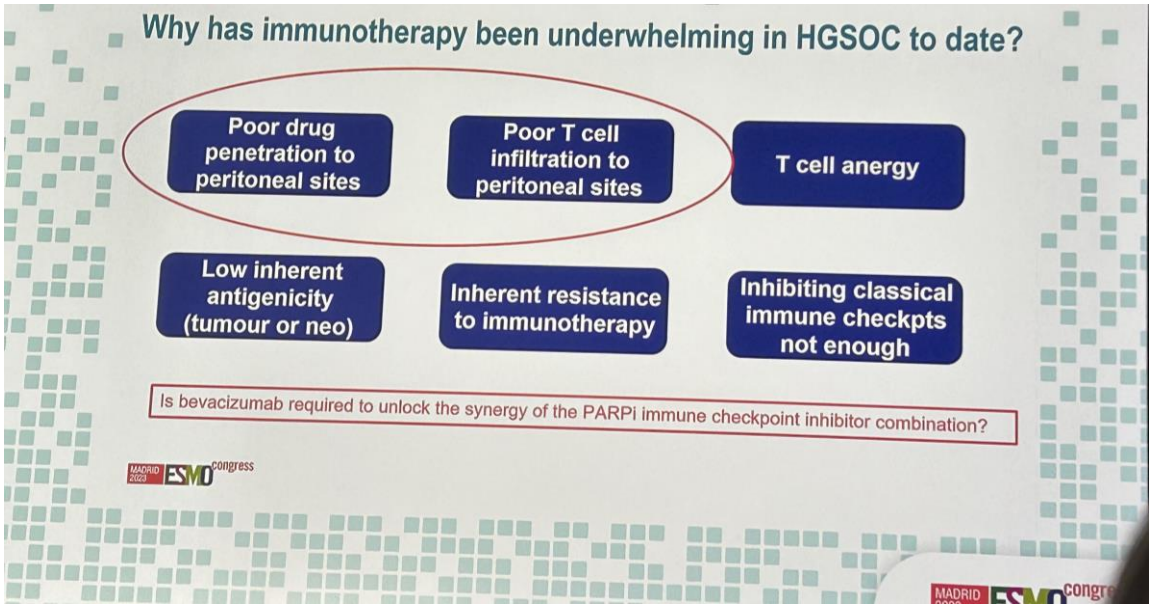
	FLAMES (senaparib)	PRIMA (niraparib)	PRIME (niraparib)	SOLO1 (olaparib)	ATHENA-MONO (rucaparib)
Any grade AEs (%)	100	99	99	98	97
Grade 3 AEs (%)	66	70	55	39	61
Most common grade ≥ 3 AEs (%)	Anaemia (29) Thrombocytopenia (29) Neutropenia (25) Leukopenia (12) Triglyceridemia (5)	Anaemia (31) Thrombocytopenia (29) ↓ platelets (13) Neutropenia (13) Fatigue (2)	Anaemia (18) ↓ Neutrophils (17) ↓ platelets (14) ↓ white cells (7) GGT increase (5)	Anaemia (22) Neutropenia (9) Fatigue (4) Diarrhoea (3) Abdominal pain (2)	Anaemia† (29) Neutropenia (15) ↑ ALT/AST (11) Thrombocytopenia (7) Asthenia/fatigue (5)
Dose interruptions due to AEs (%)	77	80	63	52	61
Dose reductions due to AEs (%)	63	71	40	48	49
Discontinuations due to AEs (%)	4*	12	7	12	12

The next presenter was Charlie Gourley, Professor and Honorary Consultant in Medical Oncology, The University of Edinburgh, Scotland

The above is showing the side effects of various PARP-inhibitors. There is no direct comparison and FLAMES with senaparib has only been used in a Chinese population. Comment from Charlie Gourley Maybe we ought to use bev. to activate T-cells?

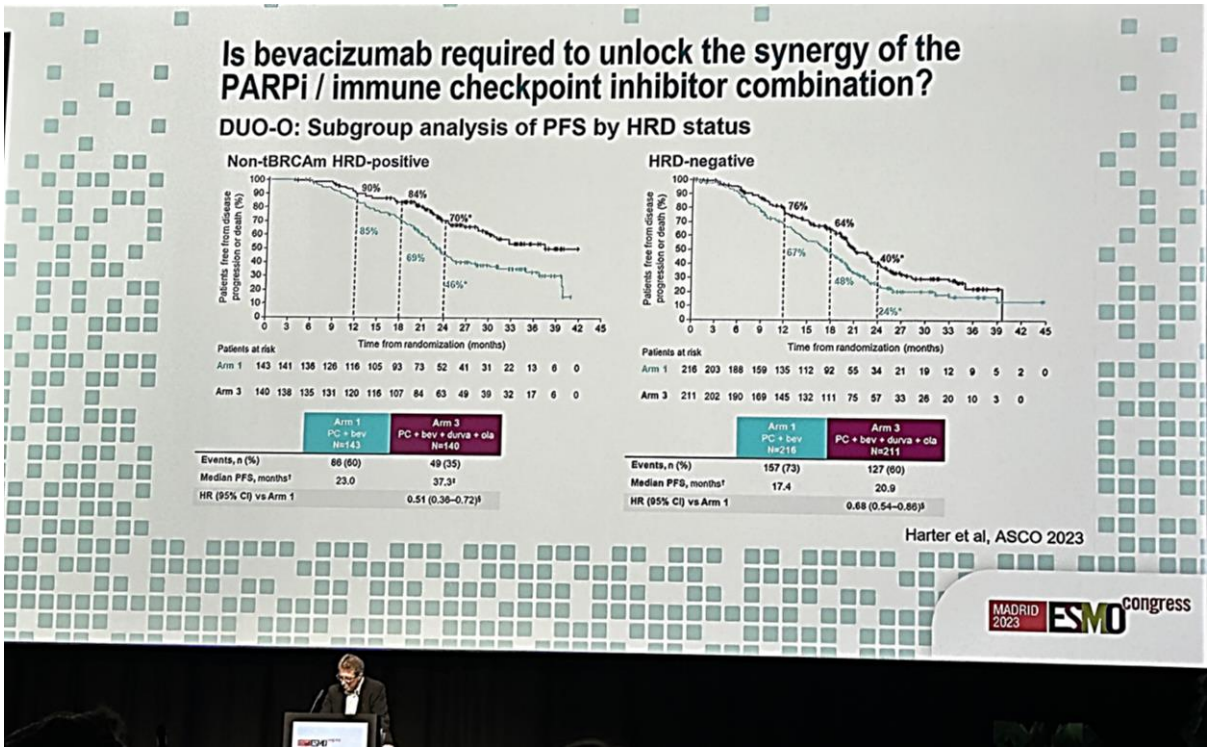


Primary Endpoint Outcome	CT + CPI		CT + CPI + BEV		CT + CPI + PARPi		CT + CPI + PARPi + BEV
	1L	≥ 2 L	1L	≥ 2 L	1L	≥ 2 L	1L
Negative	JAVELIN 100	JAVELIN 200	IMAGYN050	ATALANTE		ANITA	
Positive							DUO-O
Pending				AGO OV 2.29	OV-43 FIRST ATHENA	NItCHE	OV-43 FIRST ATHENA

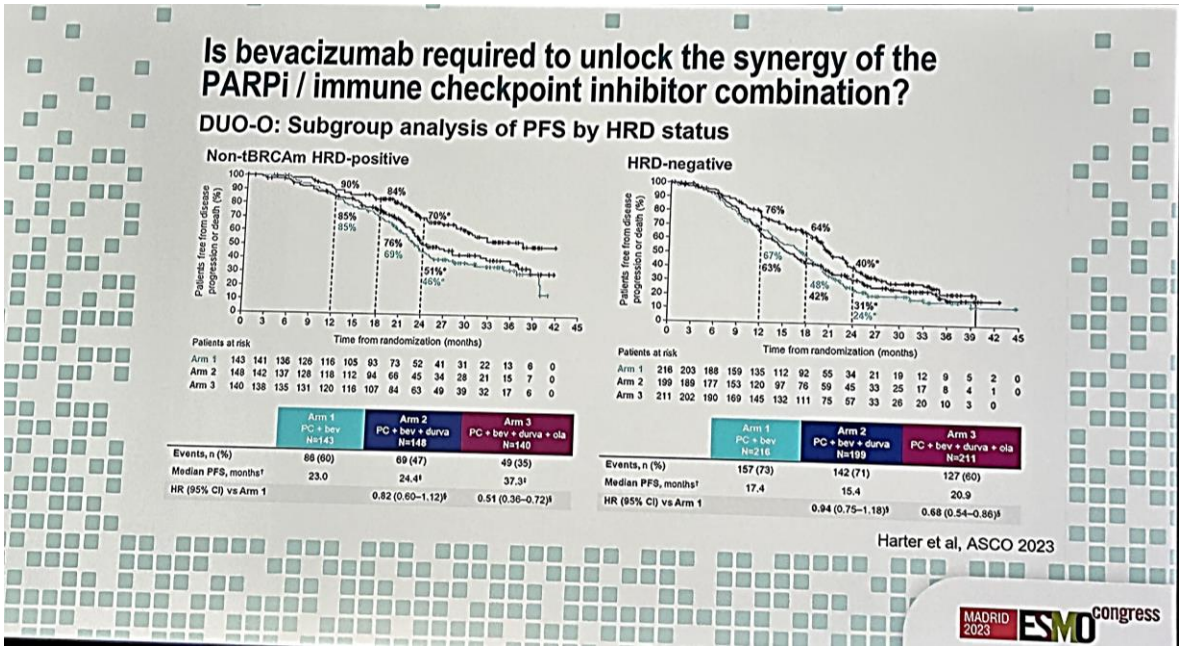


The question here is if bevacizumab is required to unlock the synergy of the PARP immune checkpoint inhibitor combination?

Even though a trial is negative, we can still learn from it. Immune checkpoint inhibitors work well in many diseases, among them cervical cancer and endometrial cancer, but not yet in high grade ovarian cancer.



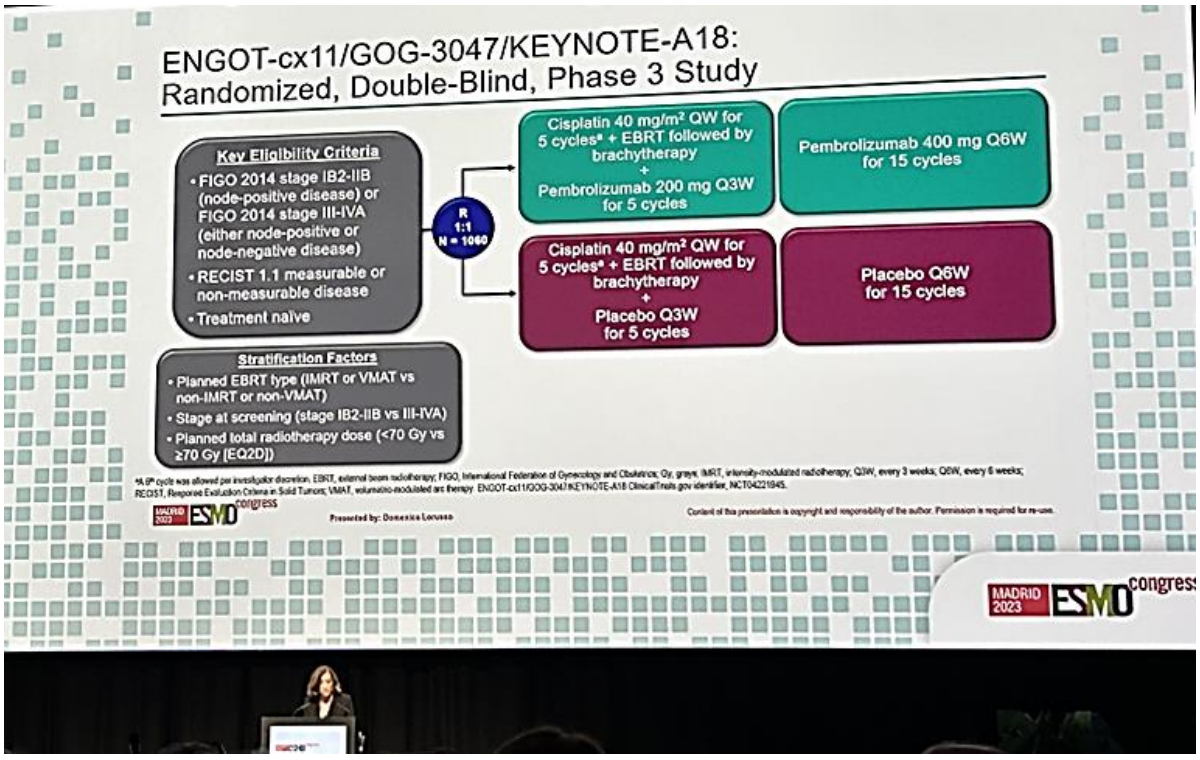
The above slide shows the results of the DUO-O study where bev. is added to durvalumab (PLD-1) and olaparib (PARP) in the 3rd arm showing a HR of 0.54 in the HRD positive arm and 0.68 in the HRD negative arm.



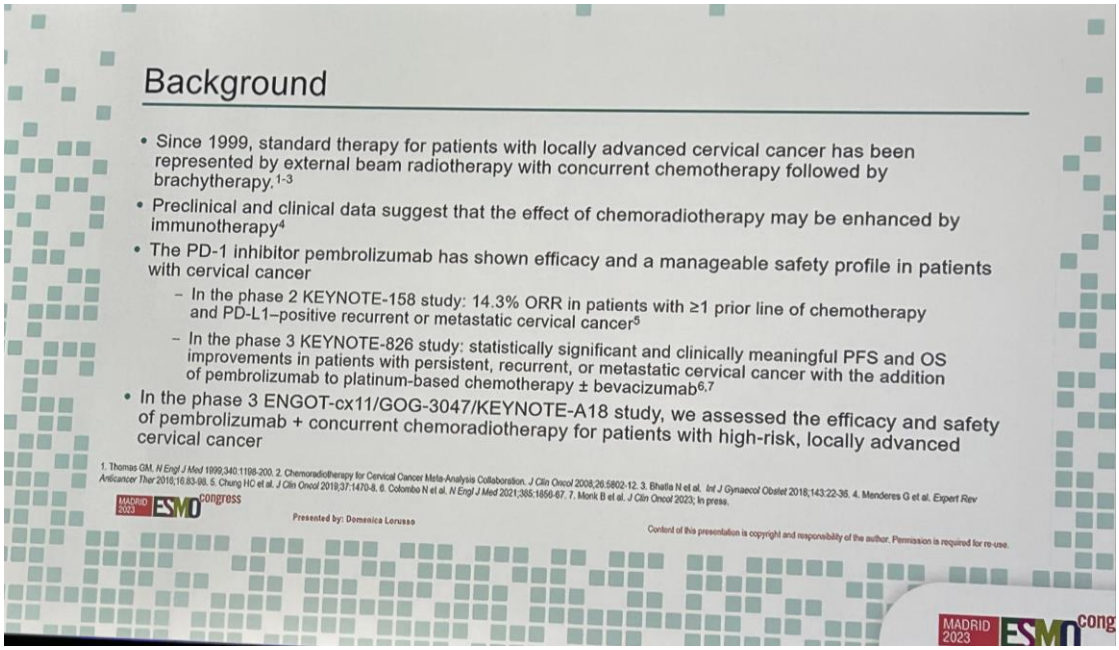
Here we see the results of all three arms. The best results are where olaparib (PARP) is added to chemo, bev. and durvalumab.

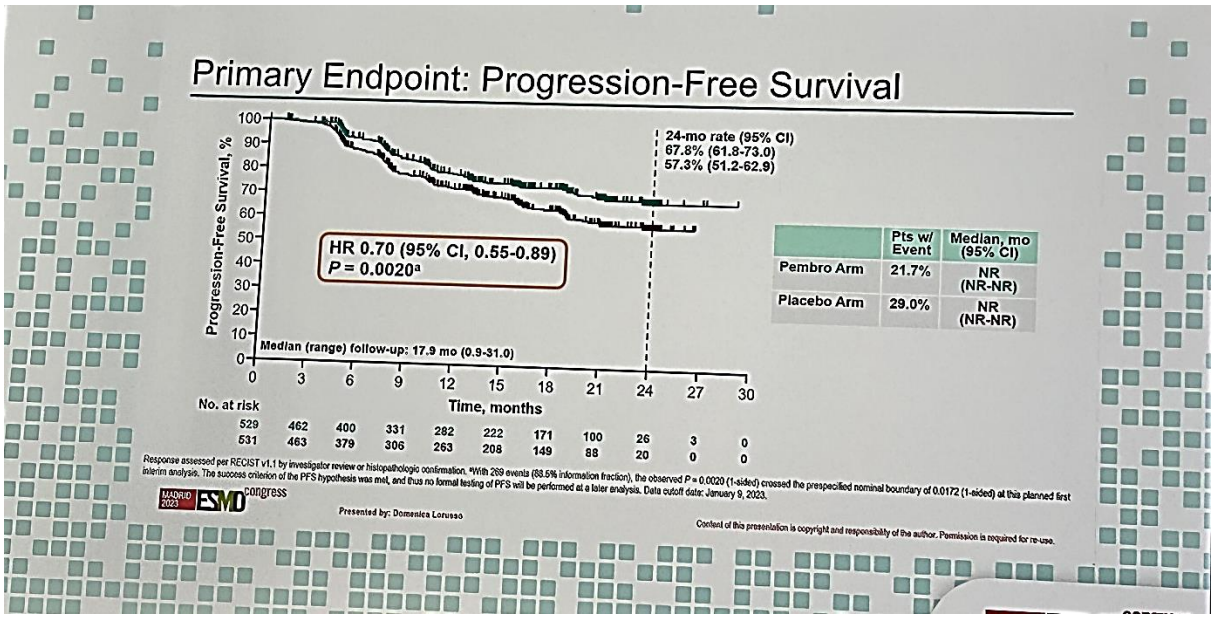
News for treatment of Cervical Cancer.

Presenter Domenica Lorusso, Professor of Obstetrics and Gynaecology at the Catholic University of Sacred Heart, Milan

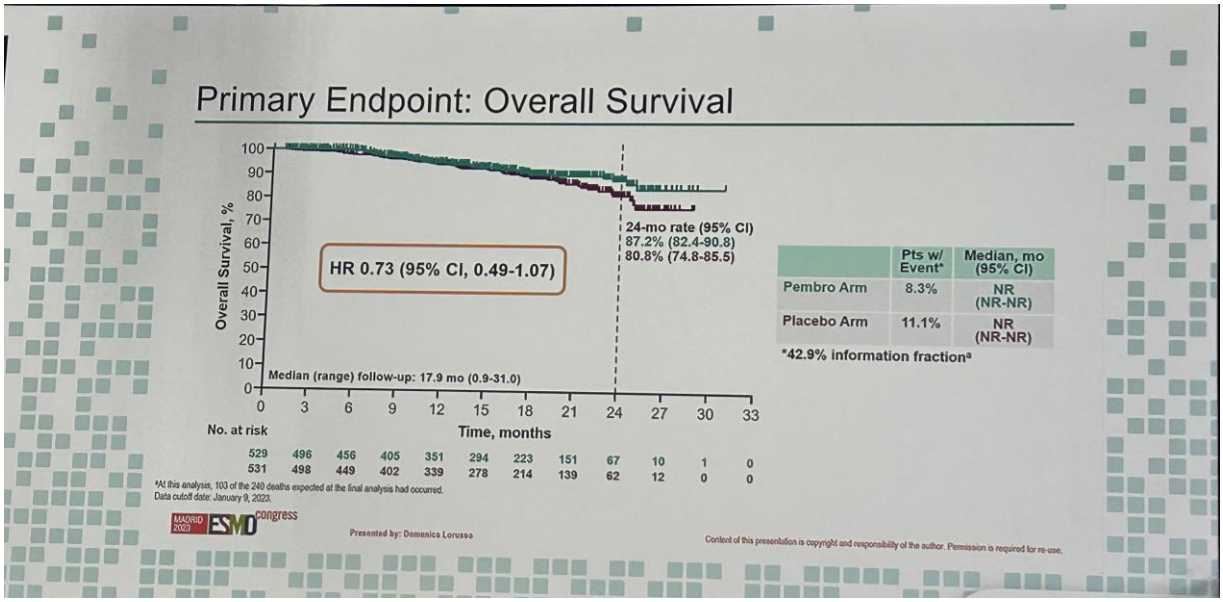


As you will see the PD-1 inhibitor Pembrolizumab is added to the treatment in the 2nd arm of this study.

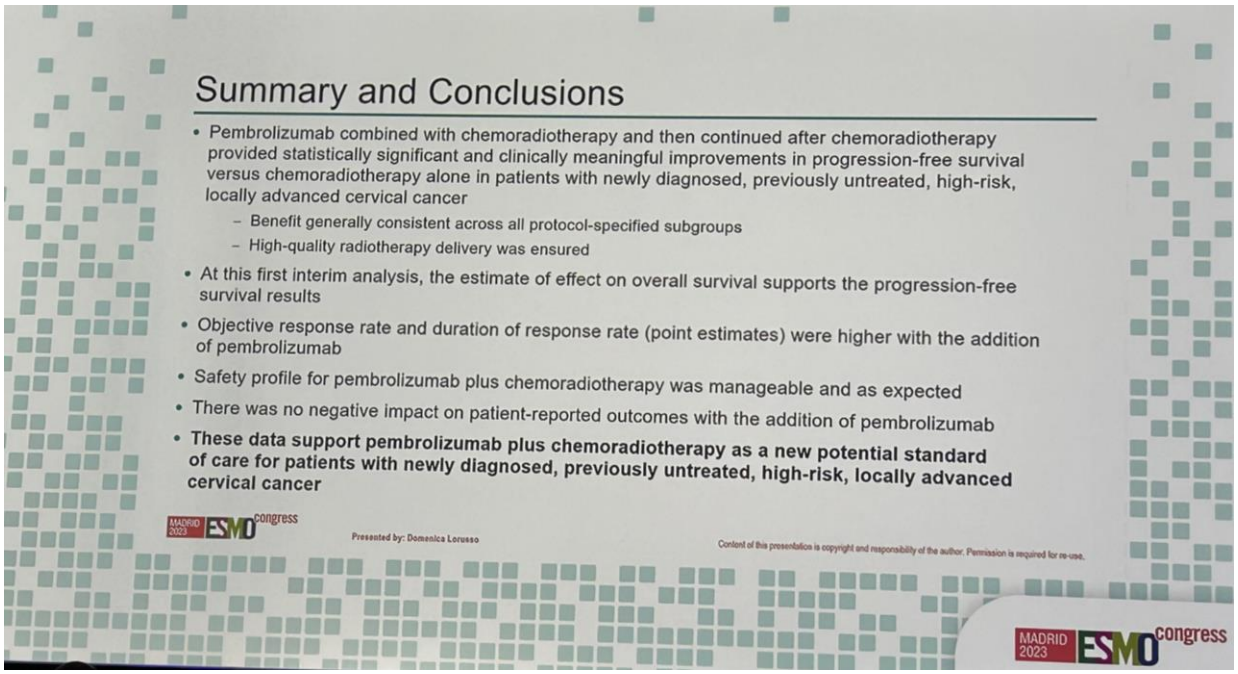




Above is PRS – progression free survival. Below is OS – Overall survival



Here we get overall survival. It is not an impressive result, but it is a positive trial.



Do we enter a new area with big data and AI - Artificial Intelligence?

This session was extremely interesting but also a bit scary. It started out with configuring a deep neural network – a so-called DNN. The DNN is continually asked to perform the task based on the input data. Provide feedback to the DNN on whether the task was executed correctly or not. The DNN adjusts its behavior based on the feedback until the task can be performed well enough.

The presenter talked about digital individuals and digital patients:

Digital patients are us, as we increasingly measure our health, wellness, and now with track apps, the health of others around our physical proximity spaces. Bluetooth zone around our phone is likely to become our new digital skin.

The Cinderella project was mentioned. You can read more about it at https://cinderellaproject.eu

Below you can read some statements from the website:

THE PROJECT

The use of the CINDERELLA APPROACH, by allowing patients to visualize photographs of "similar" patients submitted to the same treatment through an Artificial Intelligence tool can optimize the match of expectations the patient has before and after treatment and the satisfaction with actual results of breast cancer patients proposed for locoregional treatment.

THE FUTURE

The CINDERELLA Project is posed to receive five million euros from the European Commission during the next four years.

Apparently, AI can also be taught to have feelings. It is a brave new world, or is it? What will happen to us when AI is much wiser than us? The last statement is mine. AI might in the future be able to do wonderful things for mankind, but I think mankind should be careful.
