SUROVA Case Report Form

SUROVA STUDY SURGERY IN OVARIAN CANCER

An Worlwide Multicentric Observational Study CASES of 2018 and 2019

Primary endpoint

Compare overall survival (OS) at 5 years in patients who underwent primary cytoreductive surgery vs. neoadjuvant chemotherapy and interval cytoreductive surgery for stage IIIB-IVB ovarian cancer.

Chair & PI: Luis Chiva MD PhD Co-chair: Pilar Ordás PhD

Trial Committee: Antonio González, José Manuel Aramendía, Luisa Sánchez, Alejandro Gallego, Ángel Vizcay, José Ángel Mínguez, Enrique Chacón, Nabil Manzour, Daniel Vázquez, Teresa Castellanos

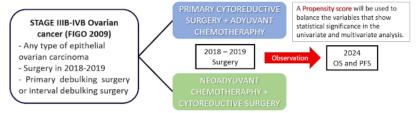
CLINICA UNIVERSIDAD DE NAVARRA

"With your collaboration, this real-life study could become one of the most comprehensive in history, examining the evolution of advanced ovarian cancer."

* Indica que la pregunta es obligatoria

1. Correo *

SUROVA Study International Observational Study



Primary endpoint: OS at 5 y between groups

Secondary endpoints: PFS at 5 y, time to first and second subsequent anticancer therapy or death,, gather information on surgical treatment approaches and decision-making processes for patients with advanced high-grade ovarian cancer in worldwide centers, extend the surgery according to the Aletti surgical complexity score, documentation of surgical complications, compare the outcomes between patients with BRCA mutations and those without this mutation and compare the outcomes between patients with HRD deficiency and those with HRD proficiency.

Some considerations before filling this form

- This a UNIQUE OPPORTUNITY to answering together some relevant and controversial questions within our Scientific Community on ovarian cancer surgery.
- We want to take an ACCURATE PICTURE of the real life concerning surgery in ovarian cancer worldwide.
- 3. The **PRECISION** of our conclusions will be proportional to the **CERTAINTY** of our answers.
- Please ensure that no cases meeting the inclusion criteria are overlooked, as this oversight
 may introduce bias, particularly for those in stage IIIB-IV who underwent surgery between
 2018 and 2019.
- Please be aware that we prioritize the confidentiality of researchers, and as such, we will not disclose or publish any information associated with the center of origin.

"Many small people, in small places, doing small things can change the world"

It is important to carefully assess the **follow-up and recurrences** in this study. The thorough evaluation of these aspects is critical to obtaining accurate results.

Please, try to **INCLUDE EVERY CONSECUTIVE PATIENT AND EVERY RELAPSE** that occurred in your center in this period of time.

RELAPSES

- To be successful, the whole study requires accuracy. Particularly, all the data related to Recurrences are fundamental.
- Since the primary endpoint is Overall Survival and the secondary endpoint Progression Free Survival, any deviation of the reality in recurrent cases is a source of bias and mistake. Therefore, every recurrence case essential. Please, avoid losing any Recurrence of your center.

Remember

- If you want to SAVE AN UNCOMPLETED FORM, fill at least all the MANDATORY ITEMS * and send the form.
- Every time you submit a form, even if it is uncompleted, you will receive a confirmation e-mail, including a copy of your response with a link to edit your form, besides you will receive a spreadsheet containing your response.
- You are allowed to re-edit your answers later by using that link so we suggest saving the e-mail or the URL of the link, if you want to edit later the case.
- We estimate that at least in the beginning, the average time to complete a case is 30 minutes.
- If you have any doubt, contact us by e-mail (Ichiva@unav.es) or whatsApp (+34630232947)

^				I +
۷.	Loca	investic	iator n	ıame ^

While only one principal investigator is allowed per center, there is the option to consider including a second investigator. The latter may be granted a certificate of participation in the study, although they will not be eligible for authorship. Contact the central principal investigator if necessary.

3.	Local investigator Last name *

4.	Country:	*
----	----------	---

9/1/24, 14:04

Marca solo un o		
Afghanista	an	
Albania		
Algeria		
Andorra		
Angola		
	nd Barbuda	
Argentina		
Armenia		
Australia		
Austria		
Azerbaijar	1	
Bahamas		
Bahrain		
Banglades	sh	
Barbados		
Belarus		
Belgium		
Belize		
Benin		
Bhutan		
Bolivia		
O Bosnia an	d Herzegovina	
Botswana		
Brazil		
Brunei		
Bulgaria		
Burkina Fa	ISO	
Burundi		
Côte d'Ivo	ire	
Cabo Verd	le	
Cambodia		
Cameroor	l	
Canada		

9/1/24, 14:04	SUROVA Case Report Form	9/1/24, 14:04	SUROVA Case Report Form
	Central African Republic	(Guinea
	Chad	(Guinea-Bissau
	Chile	(Guyana
	China	(— Haiti
	Colombia	(Holy See
	Comoros	(Honduras
	Congo (Congo-Brazzaville)	(Hungary
	Costa Rica	(Iceland
	Croatia	(India
	Cuba	(Indonesia
	Cyprus	(Iran
	Czechia (Czech Republic)	(Iraq
	Democratic Republic of the Congo	(Ireland
	Denmark	(Israel
	Djibouti	(Italy
	Dominica	(Jamaica
	Dominican Republic	(Japan
	Ecuador	(Jordan
	Egypt	(Kazakhstan
	El Salvador	(── Kenya
	Equatorial Guinea	(Kiribati
	Eritrea	(Kuwait
	Estonia	(Kyrgyzstan
	Eswatini (fmr. "Swaziland")	(Laos
	Ethiopia	(Latvia
	Fiji	(Lebanon
	Finland	(Lesotho
	France	(Liberia
	Gabon	(Libya
	Gambia	(Liechtenstein
	Georgia	(Lithuania
	Germany	(Luxembourg
	Ghana	(Madagascar
	Greece	(Malawi
	Grenada	(Malaysia
	Guatemala	(Maldives

9/1/24, 14:04	SUROVA Case Report Form	9/1/24, 14:04	SUROVA Case Report Form
	Mali		Romania
	Malta		Russia
	Marshall Islands		Rwanda
	Mauritania		Saint Kitts and Nevis
	Mauritius		Saint Lucia
	Mexico		Saint Vincent and the Grenadines
	Micronesia		Samoa
	Moldova		San Marino
	Monaco		Sao Tome and Principe
	Mongolia		Saudi Arabia
	Montenegro		Senegal
	Morocco		Serbia
	Mozambique		Seychelles
	Myanmar (formerly Burma)		Sierra Leone
	Namibia		Singapore
	Nauru		Slovakia
	Nepal		Slovenia
	Netherlands		Solomon Islands
	New Zealand		Somalia
	Nicaragua		South Africa
	Niger		South Korea
	Nigeria		South Sudan
	North Korea		Spain
	North Macedonia		Sri Lanka
	Norway		Sudan
	Oman		Suriname
	Pakistan		Sweden
	Palau		Switzerland
	Panama		Syria
	Papua New Guinea		Taiwan
	Paraguay		Tajikistan
	Peru		Tanzania
	Philippines		Thailand
	Poland		Timor-Leste
	Portugal		Togo
	Qatar		Tonga

9/1/24, 14:04	SUROVA Case Report Form
	Trinidad and Tobago
	Tunisia
	Turkey
	Turkmenistan
	Tuvalu
	Uganda
	Ukraine
	United Arab Emirates
	United Kingdom
	United States of America
	Uruguay
	Uzbekistan
	Vanuatu
	Venezuela
	Vietnam
	Yemen
	Zambia
	Zimbabwe
P	atient's basic data
•	ationt 3 basic data
5.	Center Code (provided by the central investigator) *
6.	Patient consecutive number of order *
	For instance, if the provided Center Code is: CUN (Clinica Universidad de Navarra); we will number patients as: CUN1, CUN2, CUN3, CUN4etc
7.	Patient's date of birth *
	Ejemplo: 7 de enero del 2019

/1/24,	14:04	SUROVA Case Report Form

3.	Date of the primary surgery (maximal effort cytorreduction surgery) in case of primary cytorreduction or Date of the first cycle of neoadjuvant chemotherapy (cases 2018-2019)	7
	Ejemplo: 7 de enero del 2019	

Inclusion criteria and exclusion criteria

All the power of this study relies on the adequate fulfillment of these strict criteria to avoid confounding variables that may rest value to the conclusions. We have designed these criteria in a similar way to a prospective randomized trial. Please, try to be very meticulous with patient selection.

9. Inclusion criteria

All the items must be checked and confirmed to include the patient in the study. Check all that apply

Note that Stage IIIb-IVb exclude patients with positive nodes and microscopic or absent peritoneal disease

Selecciona todos los que correspondan.
Patient >18 years old
ECOG Performance Status 0-1 at the time of the surgery (Primary or Interval)
Invasive epithelial ovarian cancer, fallopian tube carcinoma, or primary peritoneal carcinoma in stage FIGO IIIB-IVB , suspected or histologically confirmed and newly
diagnosed.
Patient underwent primary surgery or first course of neoadjuvant chemotherapy
between January 1, 2018 and December 31, 2019
ASA score 1 or 2 at the time of the surgery. ASA 3 only if ECOG 0
Surgery performed with an attempt of maximal effort
The surgeon must be a certified or non-certified gynecologic oncologist or a surgical
oncologist
Based on all available information before the surgery (primary or interval), the patient was considered completely resectable, at least in the abdomen (For instance, cases of suspicious axillary, internal mammary, or supraclavicular nodes are accepted)
Adequate bone marrow function: Absolute neutrophil count (ANC) ≥ 1.5 x 109/L, Platelets>100.000 and Hb ≥8 gr/dl
Preoperative imaging (either CT, whole-body MRL or PET-CT) excluding unresectable

Surgical report on residual disease after surgery

disease as per ESGO criteria.

Initial evaluation before first therapeutic decission

As this is a retrospective study, every effort is necessary to attempt to understand in detail the situation of each patient. This will enable a more balanced comparison between the groups of primary surgery and neoadjuvant therapy.

9/1/24, 14:04	SUROVA Case Report Form	
12.	Race	
	Marca solo un óvalo.	
	Caucasian	
	Asian	
	Latin American	
	African	
	Not reported	
	Other	
13.	BMI (kg/m2):	

How much time passed between the initial symptoms and the diagnosis of

ovarian cancer? (months)

9/1/24, 14:04

SUROVA Case Report Form

9/1/24, 14:04

SUROVA Case Report Form

15.	Performance	status a	at DIAGNOSIS	(ECOG PS
IJ.	r en lonnance	Status ((LCCC)

Be aware we are asking here the ECOG score at the time of the diagnosis, not the surgery.

Score	Patient Status
0	Fully active, able to carry on all pre-disease performance without restriction
1	Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g., light house work, office work
2	Ambulatory and capable of all self-care but unable to carry out any work activities; up and about more than 50% or waking hours
3	Capable of only limited self-care; confined to bed or chair more than 50% of waking hours
4	Completely disabled; cannot carry on any self- care; totally confined to bed or chair

Marca solo un óvalo.

ECOG 0
ECOG 1
ECOG 2
ECOG 3
ECOG 4
Not reported

16. Was the patient a heavy smoker? (more than 10 cigarettes per day)

Marca solo un óvalo.
YES
◯ NO
Not reported

17.	Any previous history of cancer (5 years before diagnosis, otherwise is excluded
	Marca solo un óvalo.
	Yes
	No
18.	If yes, specify (5 years before diagnosis, otherwise is excluded)
19.	Had the patient any inmunosupresive condition or disorder?
	Marca solo un óvalo.
	YES
	NO NO
	Not reported

20. Is there any preoperative condition that may modify the surgical indication or outcome? (if yes, specify, multiple responses is allowed)

Marca solo un óvalo por fila.

	Yes	No
Hypertension		
Diabetes		
Chronic pulmonary disease		
Cardiopathy		
Previous deep venous thrombosis or pulmonary embolism		
Denutrition		
Chronic infections		
Obesity		
Steroid use		
Other		

1. Does the patient have a known germline BRCA mutation or any other mutations associated with ovarian cancer before the diagnosis?

Marca solo un óvalo.

No known germline mutations have been identified in this patient

BRCA1

BRCA2

Lynch Syndrome Genes (MLH1, MSH2, MSH6, PMS2):

RAD51C and RAD51D

BRIP1 (FANCJ):

ATM (Ataxia Telangiectasia Mutated):

PALB2

Blood Tests at diagnosis



22.	CA 125	(U/ml)	at the diagnosis	
-----	--------	--------	------------------	--

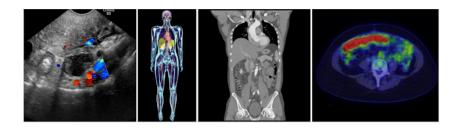
23. CEA (ng/ml) at the diagnosis

24. Serum Albumin at diagnosis the (g/dL)

25. IMAGING EVALUATION

How was evaluated the extension of the disease in this patient **at diagnosis**? (multiple answers are allowed)

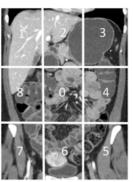
SUROVA Case Report Form



Marca solo un óvalo por fila.

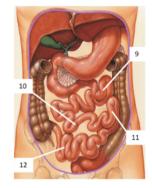
	Yes	No
Abdominal ultrasound		
Whole body MRI		
Body CT- SCAN		
PET-CT		

6. Radiological assessment of Peritoneal Cancer Index (calculate if possible)



Regions	Lesion Size
0 Central	
1 Right Upper	
2 Epigastrium	
3 Left Upper	
4 Left Flank	
5 Left Lower	
6 Pelvis	
7 Right Lower	
8 Right Flank	
9 Upper Jejunum	
10 Lower Jejunum	
11 Upper Ileum	
12 Lower Ileum	
PCI =	

Lesion Size Score			
LS 0	No tumor seen		
LS 1	Tumor up to 0.5 cm		
LS 2	Tumor up to 5.0 cm		
LS 3	Tumor > 5.0 cm or confluence		



	0 (No tumor)	1 (< 0,5 cm)	2 (0.5- 5 cm)	3 (> 5 cm)
0 Central				
1 Right Upper				
2 Epigastrium				
3 Left Upper				
4 Left Flank				
5 Left Lower				
6 Pelvis				
7 Right Lower				
8 Right Flank				
9 Upper Jejunum				

9/1/24, 14:04

SUROVA Case Report Form

Jejunum 10 Lower		
40 Lower		
Jejunum 11 Upper		
Heumpper		
ııeum 12 Lower		
Heumwer		
IIeum		

27. If possible calculate the Radiologic PCI (Range 1-39)

9/1/24, 14:04 SUROVA Case Report Form

28. Did the imaging tools show any suspicious lymph nodes in the following locations?

Marca solo un óvalo por fila.

	Yes	No
Inguinal		
Pelvic		
Paraaortic infrarenal		
Paraortic suprarrenal		
Celiac axis		
Hepatic hilum		
Cardiophrenic		
Mediastinal		
Internal Mamarial		
Supraclavicular		
Axilary		
Other		

29.	Did the	imaging	study	show	Stage	IV	disease	?
-----	---------	---------	-------	------	-------	----	---------	---

Extraabdominal disease or parenchymal disease (liver or spleen)

Marca solo un óvalo.

O YES

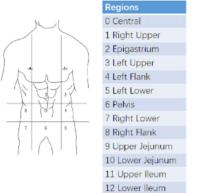
◯ NO

30.	In case there was extraabdominal disease at diagnosis, where was it located?
	(multiple answers are allowed)

	Yes	No
Liver parenchymal metastasis		
Splenic parenchymal metastases		
Inguinal lymph nodes		
Periocardiophrenic nodes		
Axilary nodes		
Mediastinal nodes		
Supraclavicular nodes		
Positive pleural effusion		
Pleural disease		
Lung metastases		
Brain metastases		
Bone Metastases		
Localized skin disease		
Abdominal wall infiltration		
Soft extraabdominal tissue metastases		
Other location not shown above		

If you answered other, specify
Was the patient considered resectable by imaging
Marca solo un óvalo.
YES
○ NO
Preoperative Evaluation of amount of Ascites
Marca solo un óvalo.
No
<500 cc
>500 cc
Masive ascites
Did the patient undergo a diagnostic laparoscopy?
Marca solo un óvalo.
YES
NO

5. If the patient was evaluated with **peritoneal cancer index (PCI) at the time of the diagnostic laparoscopy**, please show the results (Range 0-39)





36. If the patient was evaluated with the **Fagotti score at the time of the diagnostic laparoscopy**, please show the results (Range: 0-14)

Tumour site distribution	Laparoscopic predictive index score = 2	Laparoscopic predictive index score = 0
Peritoneal carcinomatosis	Unresectable massive peritoneal involvement plus miliary pattern of distribution	Carcinomatosis involving a limited area surgically removable by peritonectomy
Diaphragmatic disease	Widespread infiltrating carcinomatosis or confluent nodules to most of the diaphragmatic surface	Isolated diaphragmatic disease
Mesenteric disease	Large infiltrating nodules or involvement of the root of the mesentery assumed based on limited movements of various intestinal segments	Small nodules potentially treatable with argon-beam coagulation
Omental disease	Tumour diffusion up to the large curvature of the stomach	Isolated omental disease
Bowel infiltration	Bowel resection assumed to be required or miliary carcinomatosis at the mesenteric junction	No bowel resection required and no miliary carcinomatosis at the mesenteric junction
Stomach infiltration	Obvious neoplastic involvement of the gastric wall	No obvious neoplastic involvement of the gastric wall
Liver metastasis	Any surface lesions	No surface lesions

37.	If the patient was not evaluated neither by PCI or Fagotti Score, after reviewing the pt information, How was the <i>SURGEON</i> 'S perspective of the preoperative volume of disease? (either by imaging or laparoscopy)
	Marca solo un óvalo.
	Low burden of disease
	Medium burden of disease
	High burden of disease
38.	Did the patient have a preoperative biopsy before Primary citorreduction or Neoadjuvant Chemotherapy?
	Marca solo un óvalo.
	YES
	NO

39. Please indicate the histology of the biopsy:

High grade serous	1	Low grade serous	100 Page 100		
	2			. 1	1
3.11				$\gamma = 1$. 0
	Υ.	70			
			, a		
Endometrioid	Clear cel	1000	SP C	lucinous	
			9		
			3		
16	, 6				Acres 1

SUROVA Case Report Form

Marca solo un óvalo.

Serou:	S
--------	---

Endometrioid

	Clear	се
--	-------	----

Mucinous

Others

40. Grade of the tumor on biopsy

Marca solo un óvalo.

Low grade (G1-G2)

High grade (G3)

Not reported

41. Immunohistochemistry report at diagnosis

	Positive	Negative	Inconclusive	Mutated	No reported
WT-1					
p53					
p16					
Estrogen Receptor					
Progesterone Receptor					
HNF1 Beta					
PAX-8					
Napsine					

42	Ki-67	(%) (v	alues	among	1	and	100	3)

43. Before making any tumor board decision, how did the team assess the surgical complexity required for the patient at that moment?

Low Complexity: 1 to 3 points; Moderate Complexity: 4-7 points; High Complexity >= 8 points

Procedure	Points*
TH-BSO	1
Omentectomy	1
Pelvic lymphadenectomy	1
Paraaortic lymphadenectomy	1
Pelvic peritoneum stripping	1
Abdominal peritoneum stripping	1
Small bowel resection	1
Large bowel resection	2
Diaphragm stripping or resection	2
Splenectomy	2
Liver resection	2
Rectosigmoidectomy with reanastomosis	3
Abbreviations: CS, complexity score; TH-BSO, total hys bilateral salpingo-oophorectomy. *Surgical scoring: low, 1 to 3 points; moderate, 4 to 7 points.	

			óval	

	Low complexity
\subset	Moderate complexit
	High complexity

44. After reviewing the case in the multidisciplinary tumour board, what was the * final decision?

Marca	solo	un	óvalo.

Primary cytorreductive surgery	Salta a la pregunt	a 61
Negadiuvant chemotherapy and in	nterval debulking	Salta a la pregunta

Neoadjuvant chemotherapy

To be filled out only for patients who started with neoadjuvant chemotherapy; otherwise, jump to the section of 5 the questionnaire

5. What were the reasons for selecting neoadjuvant chemotherapy? Check all that apply; several answers are allowed

Marca solo un óvalo por fila.

	Yes	No
Age of the patient		
Fragility (ECOG>1)		
High Burden of abdominal disease		
Unresectability		
The surgery needed by the patient was considered of high complexity		
High risk for surgical morbidity and mortality		
Even though the disease was resectable, there was not a surgeon at that moment able to perform it		

46. <u>How many courses of chemotherapy</u> were delivered to the patient before the interval debulking?

47.	What schema of neoadjuvant chemotherapy did the patient undergo?
	Marca solo un óvalo.
	Carboplatin AUC5-6 / paclitaxel 175 mg/m² q21
	Carboplatin AUC5-6 / docetaxel 75 mg/m² q21 (cases of contraindications to paclitaxel)
	Carboplatin AUC 5-6, q21 (case of contraindications of combination chemotherapy Otro:
48.	Did the patient receive Bevacizumab along with the neoadjuvant chemotherapy ?
	Marca solo un óvalo.
	YES
	◯ NO
49.	If the previous answer was Yes, then how many courses of
	chemotherapy with Bevacizumab did the patient receive before surgery ?
50.	Please indicate the <u>date and value of the CA 125</u> , (DD/MM/YY; value) Before neoadjuvant CHEMOTHERAPY
51.	Please indicate the <u>date and value of the CA 125</u> , After the first course (DD/MM/YY; value)
52.	Please indicate the <u>date and value of the CA-125</u> , After the second
	course (DD/MM/YY; value)

53.	Please indicate the <u>date and value of the CA 125</u> , After the third course (DD/MM/YY; value)
54.	Please indicate the <u>date and value of the CA 125</u> , After the last course of neoadjuvant Chemotherapy , regardless of the number of courses. (DD/MM/YY; value)
55.	Please calculate if posible the KELIM score for Neoadjyuvant CHEMO at https://www.biomarker-kinetics.org/CA-125-neo (optional)

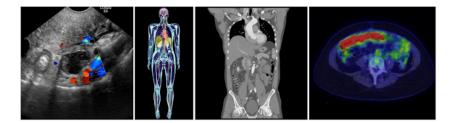
CA-125 KELIM™ is calculated with at least 3 CA-125 values measured within the first 100 days (or less) after chemotherapy start. https://www.biomarker-kinetics.org/CA-125-neo

9/1/24, 14:04

56. IMAGING EVALUATION after neoadjuvant Chemotherapy

How was evaluated the extension of the disease in this patient **after Neoadjuvant chemotherapy and before surgery** ? (multiple answers are allowed)

SUROVA Case Report Form



Marca solo un óvalo por fila.

	Yes	No
It was not evaluated by imaging		
Abdominal ultrasound		
Whole body MRI		
Body CT- SCAN		
PET-CT		

57. After the the neoadjuvant chemotherapy, before surgery, **how was the**Radiological response of the disease according to RECIST?

Marca solo un óvalo.

Complete clinical response
Partial clinical response
Stable disease
Progressive disease

8. Did the patient experience any adverse event (Grade ≥ 3) due to the neoadjuvant chemotherapy?

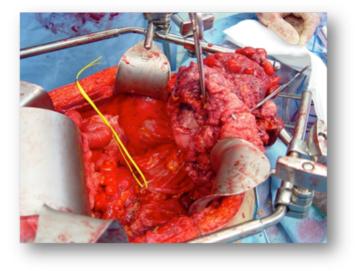
Grade	Intervention
Mild	Clinical or diagnostic observations only
2 Moderate	Local or noninvasive intervention indicated
3 Severe	Hospitalization indicated
Life-threatening	Urgent interventions indicated
5 Death	Death related to adverse events
YES NO	
What was the surgical decision	on after neoadjuvant chemotherapy
Marca solo un óvalo.	
She was operated after being	g considered a candidate for complete resection.
She was operated after bein	g considered a candidate for at least partial resection.
She was not operated becau	ise she was progressing.
She was not operated becau	se her disease was considered unresectable
She was not operated becau	ise she was deemed very fragile
She was not operated due to	o other reasons.
	perated, specify why
f the patient was finally not o	poration, opening initial
1	Mild Moderate Severe Life-threatening Death Marca solo un óvalo. YES NO What was the surgical decision Marca solo un óvalo. She was operated after bein She was not operated becaut She was not operated becaut

Surgical procedure

This questionnaire section is applicable to both patients who underwent primary surgery and those with interval debulking surgery.

SUROVA Case Report Form

- As the study focuses on the comparative analysis of two distinct surgical procedures conducted at different times, it is imperative for us to approach the description of events with precision and caution.
- Consequently, this section holds significant importance, serving as a pivotal factor in ensuring an accurate and faithful representation of the observed events.
- The operating report should be reviewed in detail to understand how was the operation carried out.



Type of procedure	
Marca solo un óvalo.	
Primary debulking	
Interval debulking	
Last CA 125 before surgery	
	Marca solo un óvalo. Primary debulking Interval debulking

63.	Date of the surgery *
	Ejemplo: 7 de enero del 2019
64.	How was the surgical approach of this case? Mark only one oval
	Marca solo un óvalo.
	Open
	Robotic
	Laparoscopy
	Other or combination
65.	The Surgeon that performed the procedure can be described as Mark only one oval
	Marca solo un óvalo.
	Senior surgeon in gyn oncology (>10 years after gyn-onc training)
	Junior surgeon in gyn oncology (<10 years after gyn-onc training)
	Fellow in gyn oncology assisted by Senior or Junior surgeon
	Resident assisted by Senior or Junior surgeon
	Surgical Oncologist
	General gynecologist
	Other
66.	Estimation of Ascites Volume at the procedure
	Marca solo un óvalo.
	No Ascites
	<500
	>500
	Massive ascites

SUROVA Case Rea	port Form	9/1/24, 14:04	SUROVA Case Report Fo

67. Frozen section diagnosis Histologic type, only if frozen secction was ordered

Marca solo un óvalo.		
Not ordered		
Inconclusive		
Border-line tumor		
Carcinoma		
Low grade carcinoma		
High grade carcinoma		

68. Tumor involvement-surgical findings

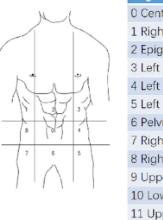
Marca solo un óvalo por fila.

	Yes	No
Right ovary		
Right tube		
Left ovary		
Left tube		
Douglas		
Vagina		
Uterus		
Bladder/ureter		
Sigmoid/Rectum		
Recto-vaginal septum		
Pelvic wall		
Pelvic nodes		
Paraaortic nodes		
Right gutter		
Left gutter		
Small bowel		
Omentum		
Large bowel		
Appendix		
Small bowel mesentery		
Large bowel mesentery		

Right diaphragm

	;	SUROVA Case Report Form
Right diaphragm Left diaphragm		-
Left diaphragm Liver surface		-
Liver surface Liver		-
parenchyma Liver		_
parenchyma Hepatic hilium		_
nodes Hepatic hilium		_
nodes Lesser		_
omentum Lesser		_
omentum Stomach		-
Stomach Pancreas		-
Pancreas Spleen		-
Spleen Celiac nodes		-
Celiac nodes Inguinal nodes		-
Inguinal nodes Cardiophrenic		-
nodes Cardiophrenic		_
nodes Abdominal wall		_
Abdominal wall Skin		-
Skin Trocar sites		-
Trocar sites		-

9. Peritoneal Cancer Index (Range 0-39).



Regions			
0 Central			
1 Right Upper			
2 Epigastrium			
3 Left Upper			
4 Left Flank			
5 Left Lower			
6 Pelvis			
7 Right Lower			
8 Right Flank			
9 Upper Jejunum			
10 Lower Jejunum			
11 Upper Ileum			
12 Lower Ileum			

Lesion Size Score

0 No Tumor

1 Tumors up to 0.5 cm

2 Tumors up to 5 cm

Tumors>5 cm or

confluence

3

Marca solo un óvalo por fila.

	0 (no)	1 (<0.5cm)	2 (0.5- 5cm)	3 (>5cm)
Central				
Right upper				
Epigastrium				
Left upper				
Left flank				
Left lower				
Pelvis				
Right lower				
Right flank				
Upper jejunum				
Lower jejunum				
Upper ileum				

Lower

9/1/24, 14:04

ileum Lower	
ileum	

SUROVA Case Report Form

70. PCI final score (Range 0-39)

71. Surgical procedures that were carried out

Yes	No
	Yes

	Hepatic hilium nodes Hepatic hilium nodes						73.	Residual disease in	the <u>ABI</u>	DOMINAL	CAVITY at	the end of	the sur	gery *
	Diaphragmatic Diaphragmatic stripping stripping							This is an essential ans Marca solo un óvalo.	wer, pleas	se try to be a	accurate			
	Diaphragmatic Diaphragmatic resection resection							No macroscopic 0.1-0.5 cm (millia						
	Splenectomy Splenectomy							0.6-1 cm		,				
	Partial Partial pancreatectomy pancreatectomy							>1cm Not reported						
	Liver capsule Liver capsule resection resection													
	Atypical liver Atypical liver resection resection						74.	Reason of incomple Marca solo un óvalo por	_	ery				
	Partial hepatectomy Partial hepatectomy								Yes	No				
	Cholecistectomy Cholecistectomy							Diffuse serosal spread						
	Peritonectomy Peritonectomy Morrison Morrison							Liver parenchymal metastasis						
	Pericardiophrenic Pericardiophrenic nodes nodes							Hepatic hilium						
	Inguinal nodes Inguinal nodes							Pancreatic metastasis						
	Trocar site resection Trocar site resection							Celiac axis						
72.	Residual disease at th		_	=	TION OF THE BO	ODY*		Supradiaphragmatic (Thoracic disease, including nodes)						
	This is an essential answ Marca solo un óvalo.	·		ccurate				Extra abdominal residual disease beyond the thorax						
	No macroscopic re 0.1-0.5 cm (milliar							Other						
	0.6-1 cm	a					75	If you answered oth	ar anasi	ı.				
	Not reported						73.	ii you answered our	ei, speci	iiy	_			

81. Did the patient receive HIPEC at the end of the surgery?

Marca solo un óvalo.

YES NO

9/1/24, 14:04 SUROVA Case Report Form

7.07	OUNC VA Case Report Form
82.	In case your previous answer was YES, which drug was used intraperitoneally for HIPEC?
83.	At what temperature was set the chemotherapy infusion (Celsius degrees)
84.	For how long was the chemotherapy infused (min)?
85.	Did the patient receive HIPEC under a clinical trial? Marca solo un óvalo. YES NO

88.

Estimated blood loss (cc)

86. Intraoperative complications.

Check all that apply. If the patient had no complications, LEAVE IT BLANK.

Definitions					
Grade 1	Any deviation from the ideal intraoperative course without the need of any additional treatment or intervention				
Grade 2	Any deviation from the ideal intraoperative course with the need of any additional treatment or intervention not lifethreathening and not leading to permanent disability				
Grade 3	Any deviation from the ideal intraoperative course with the need of any additional treatment or intervention life-threathening and/or leading to permanent disability				
Grade 4	Any deviation from the ideal intraoperative course with death of the patient				

SUROVA Case Report Form

	1	2	3	4
Intraoperative bleeding, patient needs transfusion during surgery				
Ureteral injury				
Bladder injury				
Vascular injury				
Bowel injury				
Nerve injury				
Other:				

87.	Duration of the whole surgical procedure	(minutes)
-----	--	-----------

Number RBC	units tra	nfused du	ring the	surgical _l	oroc
Was the Patie	ent trans	fered to th	e ICU aft	er the pro	cec
Marca solo un	óvalo.				
YES NO					
Patients abar	ndoned th	ne OR with	1:		
Several answers	s are allow	red			
		a.			
	valo por fil				
Marca solo un ó	valo por fil	a.			
Marca solo un ó Arterial line Central IV	valo por fil	a.			
Arterial line Central IV Line	valo por fil	a.			
Arterial line Central IV Line NG tube	valo por fil	a.			
Arterial line Central IV Line NG tube Foley cath	valo por fil	a.			
Central IV Line NG tube Foley cath Epidural cath Endotracheal	valo por fil	a.			
Arterial line Central IV Line NG tube Foley cath Epidural cath Endotracheal tube	valo por fil	a.			

2.	Length of stay of the patient	at the hospital(days)

93.	Posto	perative	com	plications

Marca	solo	un	ova	(

____ YES

ONO

94. Postoperative complications (within 30 days after surgery)

IF THE PATIENT HAD NO COMPLICATIONS, PLEASE, LEAVE IT BLANK. Clavien-Dindo Classification

	Definitions
ı	Any deviation from the normal postoperative course without the need for pharmacological treatment other than the "allowed therapeutic regimens", or surgical, endoscopic and radiological interventions
П	Requiring pharmacological treatment with drugs beyond those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
Ш	Requiring surgical, endoscopic or radiological intervention.
IV	Life-threatening complication requiring critical care management; CNS complications including brain haemorrhage and ischemic stroke (excluding TIA), sub-arrachnoidal bleeding.
V	Death of a patient

	1	2	3	4	5
Fever					
Post operative bleeding, patient needs transfusion					
Bladder fistula					
Ureteral fistula					
Urinary infection					
Hematuria					
Bladder dysfunction					
Urinary incontinence					
Small bowel fistula or leakage					

Large bowel Large bowel tistula or leakage fistula or leakage			
Constipation/ileus Constipation/ileus			
Bowel obstruction Bowel obstruction			
Pelvic or Pelvic or abdominal abdominal abscess abscess			
BVT			
Pulmonary Pulmonary embolism embolism			
Pneumonia Pneumonia			
Pleural effusion Pleural effusion			
Lymphorrhagia Lymphorrhagia			
Chylous ascites Chylous ascites			
Abdominal wall Abdominal wall infection of any infection of any type type			
Eventration or Eventration or evisceration evisceration			
Moderate/Severe Moderate/Severe Vaginal bleeding Vaginal bleeding			
Vaginal cuff Vaginal cuff cellulitis cellulitis			
Vaginal cuff Vaginal cuff defiscence dehiscence			
Readmission to Readmission to ICU			
Re-intervention Re-intervention			
Death Death			
Other Other			

98.	Final histology in the Pathology report This a crucial item. Please try to be precise. Mixed tumours are allowed if the show these histological types. Mark only one oval
	Marca solo un óvalo.
	Serous Endometrioid Clear cell Mucinous Other
99.	Final tumor grade This a crucial item. Please try to be precise. Mark only one oval Marca solo un óvalo. Low grade (G1-G2) High Grade (G3)

100. Tumor involvement in the final report

Marca solo un óvalo por fila.

	Yes	No
Right ovary		
Right tube		
Left ovary		
Left tube		
Douglas		
Vagina		
Uterus		
Bladder/ureter		
Sigmoid/Rectum		
Recto-vaginal septum		
Pelvic wall		
Pelvic nodes		
Paraaortic nodes		
Right gutter		
Left gutter		
Small bowel		
Omentum		
Large bowel		
Appendix		
Small bowel mesentery		
Large bowel mesentery		

Right diaphragm

Right diaphragm Left diaphragm	
Left diaphragm Liver surface	
Liver surface Liver	
parenchyma Liver	
parenchyma Hepatic hilium	
nodes Hepatic hilium	
nodes Lesser	
omentum Lesser	
omentum Stomach	
Stomach Pancreas	
Pancreas Spleen	
Spleen Celiac nodes	
Celiac nodes Inguinal nodes	
Inguinal nodes Cardiophrenic	
nodes Cardiophrenic	
nodes Abdominal wall	
Abdominal wall Skin	
Skin Trocar sites	

To be answered ONLY FOR PATIENTS WITH NEOADJUVANT CHEMOTHERAPY.

How was the chemotherapy **response** score (**CRS**)?

J. Chemotherapy Response Score

A system for histopathologic assessment of response to neoadjuvant chemotherapy (chemotherapy response score or CRS) for high-grade serous carcinoma has been developed and validated, and shown to be highly reproducible. 23 This 3-tiered scoring system is based on assessment of the section of omentum that shows the least response to chemotherapy. The criteria are shown in Table 2.

Table 2. Criteria of the Chemotherapy Response Score

CRS 1: No or minimal tumor response

Mainly viable tumor with no or minimal regression-associated fibro-inflammatory changes, # limited to a few foci; cases in which it is difficult to decide between regression and tumor-associated desmoplasia or inflammatory cell infiltration

CRS 2: Appreciable tumor response amidst viable tumor, both readily identifiable and tumor regularly distributed

Ranging from multifocal or diffuse regression associated fibro-inflammatory changes, with viable tumor in sheets, streaks, or nodules, to extensive regression associated fibro-inflammatory changes" with multifocal residual tumor which is easily identifiable

CR\$ 3: Complete or near-complete response with no residual tumor OR minimal irregularly scattered tumor foci seen as individual cells, cell groups, or nodules up to 2 mm in maximum size

Mainly regression-associated fibro-inflammatory changes or, in rare cases, no/very little residual tumor in complete absence of any inflammatory response; advisable to record whether "no residual tumor" or "microscopic residual tumor present"

(CRS 1
(CRS 2
(CRS 3
(Complete Pathologic Response

Marca solo un óvalo.

Regression-associated fibro-inflammatory changes: Fibrosis associated with macrophages, including foam cells, mixed inflammatory cells, and psammoma bodies; to distinguish from tumor-related inflammation or desmoplasia.

9/1/24, 14:04

CLIDOVA Coop	Donart Form
SUROVA Case	Report Form

9/1/24, 14:04

102. Immunohistochemistry at FINAL REPORT

Marca solo un óvalo por fila.

	Positive	Negative	Inconclusive	Mutated	Not reported
WT-1					
p53					
p16					
Estrogen Receptors					
Progesterone Receptors					
HNF1 Beta					
PAX-8					
Napsine					

103. Final report Ki-67 (%) (values among 1 and 100) if provided

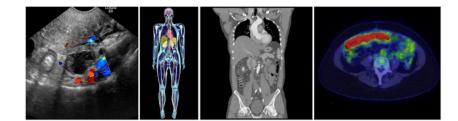
104. BRCA status

	Pathogenic	Non pathogenic	VOUS	Not reported
BRCA1 (Tumor)				
BRCA2 (Tumor)				
BRCA 1 (Germinal)				
BRCA 2 (Germinal)				

105.	Had the patient information on homologous recombination deficiency i surgical specimen?
	Marca solo un óvalo.
	Homologous recombination proficient (HRp) Homologous recombination deficient (HRd)
	One of the content of
106.	Which platform was use to determine the HRD?
	Marca solo un óvalo.
	Myriad Genetics - myChoice HRD
	Foundation Medicine
	Other
107.	What was de HRD score (if provided)
108.	FIGO Stage (2021) after full evaluation
	Marca solo un óvalo.
	☐ IIIb
	○ IVa ○ IVb
Trea	atment after surgery
Adju	uvant therapy either after primary surgery or after interval debulking

109. IMAGING EVALUATION BEFORE ADJUVANT Chemotherapy

How was evaluated the extension of the disease in this patient **AFTER THE SURGICAL PROCEDURE** ? (multiple answers are allowed)



	Yes	No
Pt was not evaluated with imaging after surgery		
Abdominal ultrasound		
Whole body MRI		
Body CT- SCAN		
PET-CT		

as residual disease identified through imaging assessment conducted ter the surgery?
arca solo un óvalo.
No imaging assesment was done
No residual disease was found
Yes, macroscopic residual disease in the abdomen
Yes, macroscopic residual disease outside the abdomen
Yes, macroscopic residual disease both in the abdomen and outside the bdomen
ow many days passed from the surgery to the first cycle of postoperative emotherapy?
hat schema of ADJUVANT chemotherapy did the patient undergo? arca solo un óvalo.
Carboplatin AUC5-6 / paclitaxel 175 mg/m² q21
Carboplatin AUC5-6 / docetaxel 75 mg/m² q21 (cases of contraindications to aclitaxel)
Carboplatin AUC 5-6, q21 (case of contraindications of combination hemotherapy)
Other
ow many courses of <u>POSTOPERATIVE</u> chemotherapy were delivered to e patient AFTER surgery
ease indicate the <u>date and value CA 125 value</u> (DD/MM/YY; value), Before DSTOPERATIVE CHEMOTHERAPY

CA-125 KELIM™ is calculated with at least 3 CA-125 values measured within the first 100 days (or less) after chemotherapy start. https://www.biomarker-kinetics.org/CA-125

Was the patient reevaluated by imaging just after finishing the chemotherapy?

Marca solo un óvalo.

\bigcirc	Yes
	No

9/1/24, 14:0

)4	SUROVA Case Report Form
121.	Was residual disease identified through the imaging assessment conducted during the post-chemo evaluation?
	Marca solo un óvalo.
	No imaging assesment was done
	No residual disease was found
	Yes, macroscopic residual disease in the abdomen
	Yes, macroscopic residual disease outside the abdomen
	Yes, macroscopic residual disease both in the abdomen and outside the abdomen
122.	Did the patient experience any adverse events (Grade ≥ 3) due to the
	POSTOPERATIVE chemotherapy?

	Grade	Intervention
1	Mild	Clinical or diagnostic observations only
2	Moderate	Local or noninvasive intervention indicated
3	Severe	Hospitalization indicated
4	Life-threatening	Urgent interventions indicated
5 Marc	Death a solo un óvalo.	Death related to adverse events

	NO

123. Did the patient receive Bevacizumab along with the adyuvant chemotherapy ?

Marca solo un óvalo.

YES

YES

ON (

127. Did the patient suffer a relapse? *

Marca solo un óvalo.

YES

NO

We don't know, patient was missed after surgery

9/1/24, 14:04 SUROVA Case Report Form

128.	If the answer was yes, when was she diagnosed the first relapse? This is a crucial item. Please try to be precise Example: December 15, 2012
	Ejemplo: 7 de enero del 2019
129.	What was the CA 125 at the time of relapse (U/ml)

130. How was diagnosed the recurrence?

Check all that apply. You may select several items

	Yes	No
Physical exam		
Ca 125		
Biopsy		
MRI		
CT scan		
PET CT		
Abdominal ultrasound		
Vaginal ultrasound		
Chest Xray		
Other		

131. **If the patient relapsed, where was the recurrence?** This is a crucial element.

SUROVA Case Report Form

Please try to be precise. Check all that apply

Marca solo un óvalo por fila.

	Yes	No
Abdominal (4 or less lesions)		
Abdominal (> 4 lesions)		
Retroperitoneal		
Thorax		
Distant metastasis outside the abdomen or thorax		

132. Where was specifically located the relapse?

Check all that apply

	Yes	No
Pelvic peritoneum		
Middle abdomen peritoneum		
Upper abdomen peritoneum		
Pelvic nodes		
Paraaortic nodes		
Suprarenal nodes		
Extraabdominal nodes		
Inguinal nodes		
Laparotomy scar		
Liver parenchima		
Spleen parenchima		
Trocar sites		
Distant metastasis (specify below)		

:04			SUR	OVA Case Report Form	9/1/24, 14:04	SUROVA Case Report Form
133.	In case there was extraabdominal disease at relapse, where was it located ? (multiple answers are allowed)		136.	What was the first therapeutic approach after relapse? Marca solo un óvalo.		
	Marca solo un óvalo po	or fila.				Secondary cytoreduction
		Yes	No			Chemotherapy
	Inguinal lymph nodes					Palliative care
	Localised skin disease					Otro:
	Periocardiophrenic nodes				137.	In case of secondary cytoreduction after diagnosis of relapse, when was the date of the surgery?
	Axilary nodes					
	Mediastinal nodes					Ejemplo: 7 de enero del 2019
	Supraclaviculal nodes				138.	Did the patient receive neoadjuvant chemotherapy for the relapse before the
	Positive pleural effusion					secondary surgery? Marca solo un óvalo.
	Pleural disease					YES
	Other location					○ NO
134.	If you have answere	ed other I	ocation, p	lease specify location of distant metastasis	139.	How was the outcome of the secondary surgery in terms of residual disease ? Marca solo un óvalo.
135.	Any commentary to	o clarify th	ne location	of relapse/s		R 0 R 0,1-1 cm R > 1 cm
					140.	Did the patient receive HIPEC at the end of the surgery? Marca solo un óvalo.
						YES NO

Marca solo un óvalo.

Complete clinical response
Partial clinical response
Stable disease

Disease Progression

9/1/24, 14:04 SUROVA Case Report Form

45. If the BRCA status was not previously evaluated, do we now have a final BRCA report on the tumor at any time?

Marca solo un óvalo por fila.

	Pathogenic	Non pathogenic	VOUS	Not reported	No
BRCA1(Tumor)					
BRCA2 (Tumor)					
BRCA1 (Germline)					
BRCA2 (Germline)					

146. Did the patient receive any maintenance therapy at the first relapse?

	Yes	No
Bevacizumab		
Niraparib		
Olaparib		
Rucaparib		
Immunotherapy		
Hormone therapy		
Other		

147. Has the patient experienced any other relapse or progression before the last

9/1/24, 14:04

151. Status at last follow-up

	follow-up at the time of filling out this form?	This is a crucial item. Please try to be precise.
	Marca solo un óvalo.	Marca solo un óvalo.
	Yes	iviai ca solo un ovalo.
	No	Alive without disease
		Alive with disease
		Death without disease
148.	If yes, please just indicate the date of the second relapse (PFS2, Time to	Death of disease
	second progression)	Missing
	Ejemplo: 7 de enero del 2019	
		152. If the patient was alive in the last contact how was her performance statu
1/0	If apply, please just indicate the date of the third line of treatment (TSST,	(ECOG PS)
177.	second subsequent therapy)	Grade ECOG
		0 Fully active, able to carry on all pre-disease performance without restriction
	Ejemplo: 7 de enero del 2019	1 Restricted in physically strenuous activity but ambulatory and able to carry out work of a light or sedentary nature, e.g. light house work, or
Las	t Contact and Final evaluation	work 2 Ambulatory and capable of all selfcare but unable to carry out any w
٨٥٥	urata completion of the information is impossible without the details of this section	activities. Up and about more than 50% of waking hours
	urate completion of the information is impossible without the details of this section. se be very careful in gathering the data."	Capable of only limited selfcare, confined to bed or chair more than soft waking hours
		4 Completely disabled. Cannot carry on any selfcare. Totally confined bed or chair
150.	Date of last contact or last follow up or death *	5 Dead
	This is a crucial item. Please try to be precise. Exmple: December 15, 2012	Marca solo un óvalo.
		0 1 2 3 4 5
	Ejemplo: 7 de enero del 2019	ECO C C ECOG 5
		153. Was the patient actively enrolled in any prospective clinical trial during the course of her illness?
		Marca solo un óvalo.
		YES
		○ NO

154.	If you answered "yes," kindly provide a reference for the trials. (Name or number of the trial or the trials)
155.	Please, share any commentary regarding the case that may help to offer relevant information
156.	"I confirm that all information provided for this case corresponds to the details documented in the clinical history, with the exception of any inadvertent errors or omissions." Marca solo un óvalo.
	Confirmed Unconfirmed
157.	To be filled by the central investigator This case includes all the requirements to be accepted
	Marca solo un óvalo.
	YES
	NO

We greatly appreciate your contribution to this study.

We believe that by working together, we can achieve some truly insightful results.

You will soon receive a copy of this questionnaire; we recommend keeping it in a secure place in case we need to refer to any details



Este contenido no ha sido creado ni aprobado por Google.

Google Formularios