

Basic data Gynaecology

Reg. No.	Not Listed <i>i</i>	(Template certificate) <i>i</i>	
Centre			
Clinical site			
Contact	<i>i</i>	Date recorded	<i>i</i>
		Date first certification	----- <i>i</i>
		Indicator year	2022

Federal state / Country	
Tumour documentation system	XML-OncoBox <i>i</i> Not yet available

Total case number Def. In line with CR 1.2.1; automatic carry-over "number / denominator" to the Indicator Sheet	Primary cases (Def. CR 1.2.1)						Non-primary cases		Total case number (Def. CR 1.2.1)		
	operated ²⁾						not operated	operated	not operated	operated (Def. CR 5.2.6)	not operated
	Not complete surgery* (ovary/Fallopian tubes/peritoneal, BOT, STIC)	Definitive surgery = staging surgery** (ovary/Fallopian tubes/peritoneal, BOT, STIC)	Including with neoadjuvant or pre-operative systemic therapy (ovary/Fallopian tubes/peritoneal)	Only staging surgery / Not complete surgery (cervix, endometrium, vulva, vagina, other)	Definitive surgery (where appr. incl. staging surgery) (cervix, endometrium, vulva, vagina, other)						
Ovarian cancer/ fallopian tubes carcinoma/ peritoneal carcinoma ¹⁾	FIGO IA	<i>i</i>	<i>i</i>		do not complete	<i>i</i>					
	FIGO IB	<i>i</i>	<i>i</i>			<i>i</i>					
	FIGO IC	<i>i</i>	<i>i</i>			<i>i</i>					
	FIGO IIA	<i>i</i>	<i>i</i>			<i>i</i>					
	FIGO IIB	<i>i</i>	<i>i</i>			<i>i</i>					
	FIGO IIIA	<i>i</i>	<i>i</i>			<i>i</i>					
	FIGO IIIB	<i>i</i>	<i>i</i>			<i>i</i>					
	FIGO IIIC	<i>i</i>	<i>i</i>			<i>i</i>					
	FIGO IV	<i>i</i>	<i>i</i>			<i>i</i>					
Total	<i>i</i>	<i>i</i>		<i>i</i>							
Borderline ovarian / Serous Tubal Intraepithelial Carcinoma (STIC)											
Cervical carcinoma *	FIGO IA1 (= T1a1)	do not complete			<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IA2 (= T1a2)				<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IB1 (= T1b1)				<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IB2 (= T1b2)				<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IIA (= T2a)				<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IIB (= T2b)				<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IIIA (= T3a)				<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IIIB (= T3b)				<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IVA (= T4)				<i>i</i>	<i>i</i>	<i>i</i>				
	FIGO IVB (= M1)						<i>i</i>				
Total					<i>i</i>						
Endometrial cancer											
Vulvar cancer											
Vaginal carcinoma											
Other (incl. sarcoma, non-carcinoma ovarian, chorion carcinoma etc.)											
						<i>i</i>		<i>i</i>		<i>i</i>	

The TNM classification of malignant tumours, 8th edition 2017, and the ICD classification ICD-10-GM 2021 (DIMDI) as well as the ICD classification ICD-O-3 (DIMDI) (topography and morphology) 2019 and the OPS classification OPS 2022 (DIMDI) are the basis for this Catalogue of Requirements.

* Note to Cervical carcinoma: The classification of cervical carcinoma is based on the FIGO classification BEFORE 2018, which is in line with the 8th edition of the TNM. FIGO classification 2018 is not taken into consideration.

** Not complete surgery in inoperable patients

*** In line with Guidelines "Diagnosis, treatment and aftercare of malignant ovarian tumours"

Processing remarks:

1) Fallopian tube and peritoneal carcinomas are classified as ovarian carcinomas (in line with S3 Guideline identical therapy). Hence, the QI for ovarian carcinomas comprises all 3 tumour entities.

2) For each patient either 1 definitive surgery or 1 "not complete" or "solely staging surgery" be counted.

Some of the fields are inter-dependent. Each line should, therefore, be completely processed from left to right and continuously from top to bottom.

Grey fields must be processed. The processing of the Excel template should be done with Microsoft Office 2010 or one of the later versions.

Microsoft Office 2007 can be used with some constraints (e.g. information buttons are not displayed). Earlier versions of Microsoft Office 2007 are not suitable for processing the Excel template. All numbers and texts must be entered manually (not using copy/paste function; the exception are data which are imported from OncoBox).

Each change to the basic data leads to a change in the Indicator Sheet. The document "Specifications Data Quality" sets out the basic principles for data assessment as part of the audit process. In particular details are given of how to deal with indicators where the target value is not met (download from www.onkozert.de; section Remarks).

Indicator Sheet Gynaecology

Centre

Reg. No.

Not Listed

Date recorded

The optional indicators for the audit year 2022 / indicator year 2021 are mandatory for the audit year 2023 / indicator year 2022.

IN	CR / GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi unclear	Target	Plausi unclear	Target Value		Data quality
1	1.2.3	Presentation tumour board	As frequent as possible presentation of patients with a genital malignoma in the tumour board	Patients of the denominator who were presented in the tumour board	Total case number (= Indicator 5)		≥ 80%		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
2		Psycho-oncological counselling (consultation ≥ 25 min.)	Adequate rate of psycho-oncological counselling	Patients of the denominator, who received psycho-oncological counselling in an outpatient or inpatient setting (consultation ≥ 25 min.)	Total case number (= Indicator 5)	< 15%	No target value		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
3		Counselling social services	Adequate rate of counselling by social services	Patients of the denominator, who received counselling from the social services in an outpatient or inpatient setting	Total case number (= Indicator 5)	< 50%	No target value		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
4	1.7.5	Share of study patients	Inclusion of as many patients as possible in studies	Patients included in a study with an ethical vote	Primary cases (= Indicator 6)		≥ 5%	> 65%	Numerator		Incomplete
									Denominator	0	
									%	n.d.	
5	1.2.1	Total case number	See target value	Total case number	----		≥ 75		Number	0	Incomplete
6a	1.2.1	Primary cases	See target value	Primary cases	----		≥ 50		Number	0	Incomplete

IN	CR / GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi unclear	Target	Plausi unclear	Target Value	Data quality	
6b	1.2.1	<u>Non-primary cases</u>	----	Non-primary cases	----		No target value		Number 0	Incomplete	
7	5.2.6	<u>Surgical</u> cases	See target value	Surgical cases	----		≥ 40		Number 0	Incomplete	
8	GL QI	Ovarian cancer : Offering of genetic testing	As frequent as possible offering of genetic testing	Primary cases of the denominator with offering of genetic testing	Primary cases ovarian carcinoma		No target value		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
9	GL QI	Ovarian cancer: Surgical staging early ovarian cancer	As often as possible complete surgical staging	Primary cases of the denominator with surgical staging with: •Laparotomy •Peritoneal cytology •Peritoneal biopsies •Bilateral adnex exstirpation •Hysterectomy, where appropriate extraperitoneales procedure •Omentectomy at least infracolic •Bilateral pelvic and paraaortal lymphonodectomy	Surgical primary cases ovarian cancer FIGO I – IIIA	< 20%	No target value		Numerator		Incomplete
									Denominator	0	
									%	n.d.	
10	GL QI	Ovarian cancer: Macroscopic complete resection advanced ovarian cancer	As often as possible macroscopic complete resection	Primary cases of the denominator with macroscopic complete resection	Surgical primary cases with an ovarian cancer FIGO IIB-IV		≥ 30%	> 90%	Numerator		Incomplete
									Denominator	0	
									%	n.d.	
11	GL QI	Ovarian cancer: Operation advanced ovarian cancer by a gynaecological oncologist	As often as possible surgical treatment by gynaecological-oncologists/specialist for gynaecology and obstetrics with the focus	Primary cases of the denominator whose definitive surgical treatment was performed by a gynaecological oncologist	Surgical primary cases ovarian cancer FIGO IIB-IV after completion of surgical treatment		≥ 80%		Numerator		Incomplete
									Denominator	0	

IN	CR / GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi unclear	Target	Plausi unclear	Target Value		Data quality
			gynaecological oncology						%	n.d.	
12	GL QI	Ovarian cancer: Post-operative chemotherapy advanced ovarian cancer	As often as possible post-operative chemotherapy for advanced ovarian cancer and chemotherapy	Primary cases of the denominator with post-operative chemotherapy	Surgical primary cases ovarian cancer FIGO IIA-IV and chemotherapy		≥ 80%		Numerator		Incomplete
								Denominator			
								%	n.d.		
13	GL QI	Ovarian cancer: First-line chemotherapy advanced ovarian cancer	As often as possible first-line chemotherapy with carboplatin and paclitaxel for initial diagnosis ovarian cancer ≥ FIGO IIA	Primary cases of the denominator with first-line chemotherapy with carboplatin and paclitaxel	Primary cases ovarian cancer FIGO IIA-IV	< 20%	No target value		Numerator		Incomplete
								Denominator	0		
								%	n.d.		
14	GL QI	Cervical cancer: Details in the pathology report in the case of first diagnosis and tumour resection	As often as possible full details in the pathology report in the case of tumour resection	Primary cases of the denominator with pathology reports with details of: <ul style="list-style-type: none"> • Histological type according to WHO • Grading • Detection/non-detection lymph and vein infiltration (L and V status) • Detection/non-detection perineural infiltrates (Pn status) • Staging (pTNM und FIGO) in the case of conized patients bearing in mind the conisation results • Depth of invasion and spread in mm in the case of pT1a1 and pT1a2 • Specification of the maximum tumor size (from pT1b1) • Minimum distance to the resection margins 	Surgical primary cases cervical carcinoma and tumour resection		≥ 80%		Numerator		Incomplete
								Denominator	0		
								%	n.d.		
15	GL QI	Cervical cancer: Details in the pathology report in the case of lymphonodectomy	As often as possible complete details in the pathology report in case of lymphonodectomy	Surgical cases of the denominator with pathology report containing details of: <ul style="list-style-type: none"> • Number of affected lymph nodes in relation to removed lymph nodes • Assignment to sampling localisation (pelvic/paraaortal) • Details of the biggest spread of the largest lymph node metastasis in mm/cm • Details of the detection/non-detection of capsul penetration by lymph node metastasis. 	Surgical cases cervical carcinoma and lymphonodectomy		≥ 80%		Numerator		Incomplete
								Denominator			
								%	n.d.		
16	GL QI	Cervical cancer: Cytological/histological lymph node staging	As often as possible cytological/histological lymph node staging	Primary cases of the denominator with cytological/histological lymph node staging	Primary cases cervical carcinoma FIGO stage ≥ IA2-IVA		≥ 60%		Numerator		Incomplete
								Denominator	0		

IN	CR / GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi unclear	Target	Plausi unclear	Target Value		Data quality
		staging							%	n.d.	
17	GL QI	Cervical cancer: Brachytherapy as a component of primary radio(chemo) therapy	As often as possible brachytherapy as a component of primary radio(chemo) therapy	Primary cases of the denominator in which brachytherapy was administered as part of primary radio(chemo) therapy	Primary cases with cervical carcinoma and primary radio(chemo) therapy, without primary Distant Metastasis		≥ 80%		Numerator		Incomplete
									Denominator		
									%	n.d.	
18 <i>optional</i>	GL QI	Histological confirmation of local recurrence	Histological confirmation as often as possible in patients with local recurrence of cervical carcinoma	Patients of the denominator with pre-therapeutic histological confirmation	Patients with cervical carcinoma and therapy of a local recurrence		< 50%	No target value	Numerator		optional - Incomplete
									Denominator		
									%	n.d.	
19	GL QI	Vulvar cancer: Details in pathology report in the case of first diagnosis and tumour resection	As often as possible full details in the pathology report in the case of resection	Primary cases of the denominator with pathology reports containing details of: •Histological type according to WHO, •Grading, •Detection/non-detection of lymph or blood vessel infiltration (L and V status), •Detection/non-detection of perineural invasion (Pn status), •Staging (pTNM), •Depth of invasion and spread in mm in the case of pT1a, three-dimensional tumour size in cm (ab pT1b), •Metric details of the minimum distance of the carcinoma and VIN from the vulvar resection margin in the histological specimen; •In the case of resection of the vulvar-vaginal or vulvar-anal transition zone and, where applicable, of the urethra metric details of the minimum distance to the vulvar-vaginal or vulvar-anal and, where applicable, urethral resection margin; •Metric details of the minimum distance to the soft tissue resection margin (basal margin)	Primary cases vulvar carcinoma with tumour resection		≥ 80%		Numerator		Incomplete
									Denominator		
									%	n.d.	
				Primary cases of the denominator with pathology report with details of: • Number of affected lymph nodes in relation to the number of removed lymph nodes					Numerator		

IN	CR / GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi unclear	Target	Plausi unclear	Target Value		Data quality
20	GL QI	Vulvar cancer: Details in pathology report in the case of lymphonodectomy	As often as possible full details in the pathology report in the case of lymphonodectomy	classified by removal localisation (inguinal/pelvic) <ul style="list-style-type: none"> • Non-detection/detection of a capsul infiltration of the lymph node metastatis and/or detection lymph node infiltrations in perinodal fatty tissue and/or the lymph node capsule (\geqpN2c) • Biggest spread of metastases (through pN details) 	Primary cases vulvar cancer with lymphonodectomy		$\geq 80\%$		Denominator		Incomplete
									%	n.d.	
21	GL QI	Vulvar cancer: Conduct inguinofemoral staging	As often as possible inguinofemoral staging for vulvar cancer \geq pT1b (no basal cell carcinoma and no verrucous carcinoma)	Primary cases of the denominator with surgical staging (systematic lymphadenectomy and sentinel biobsy) of inguinofemoral lymph nodes	Primary cases vulvar cancer \geq pT1b (no basal cell carcinoma and no verrucous carcinoma)		$\geq 90\%$		Numerator		Incomplete
									Denominator		
									%	n.d.	
22	GL QI	Vulvar cancer: Sentinel lymph nodes biopsy	As often as possible presence of the described characteristics in the case of performed sentinel surgery	Primary cases of the denominator with the following characteristics: <ul style="list-style-type: none"> • Clinical tumour size < 4 cm and • Unifocal tumour (= no multiple tumours; TNM m-symbol) and • Clinically inconspicuous lymph nodes (cN0) and • Pathohistological ultrastaging of lymph nodes (= in line with LL), only if all sentinel lymph nodes are tumor-free in the H&E staining 	Primary cases vulvar cancer and sentinel lymph node biopsy		$\geq 80\%$		Numerator		Incomplete
									Denominator		
									%	n.d.	
23	GL QI	Endometiral Cancer: Systematic lymphadenectomy for Type-I-endometrial carcinoma	No systematic lymphadenectomy (LNE) for type-I-entometrial carcinoma pT1a, G1/2, cN0	Primary cases of the denominator with a systematic lymphadenectomy	Primary cases type-I-endometrial carcinoma (ICD-0: 8380/3, 8570/3, 8263/3, 8382/3, 8480/3) pT1a, G1/2, cN0		$\leq 5\%$		Numerator		Incomplete
									Denominator		
									%	n.d.	
24	GL QI	Endometiral Cancer: Adjuvant chemotherapy for type-I-endometrial carcinoma	No adjuvant chemotherapy for type-I-endometrial carcinoma pT1a/b G1 cN0/pN0 o. pT1a/b G2 cN0/pN0	Primary cases of the denominator with adjuvant chemotherapy	Primary cases type-I-endometrial carcinoma (ICD-0: 8380/3, 8570/3, 8263/3, 8382/3, 8480/3) pT1a/b G1 cN0/pN0 o. pT1a/b G2 cN0/pN0		$\leq 5\%$		Numerator		Incomplete
									Denominator		
									%	n.d.	
					Cases operated on at the centre Primary cases with				Numerator		

IN	CR / GL	Indicator definition	Indicator target	Numerator	Population (= denominator)	Plausi unclear	Target	Plausi unclear	Target Value		Data quality
25a <i>Indication optional</i>	GL QI	Hysterectomy without morcellement for sarcoma confined to the uterus (in the centre)	Hysterectomy without morcellement as often as possible (in the centre)	Primary cases of the denominator with hysterectomy without morcellement	sarcoma confined to the uterus (ICD-O T C54, C55 IV/m morphology codes sarcoma centres), M0 with hysterectomy		No target value	> 0,01%	Denominator		optional - Incomplete
									%	n.d.	
25b <i>Indication optional</i>	GL QI	Hysterectomy without morcellement for sarcoma confined to the uterus (outside the centre)	Hysterectomy without morcellement as often as possible (outside the centre)	Primary cases of the denominator with hysterectomy without morcellement	Primary cases operated on outside the centre with sarcoma confined to the uterus (ICD-O T C54, C55 IV/m morphology codes sarcoma centres), M0 with hysterectomy		No target value	> 0,01%	Numerator		optional - Incomplete
									Denominator		
									%	n.d.	

Data quality indicators

OK	Plausible	0,00% (0)	0,00% (0)	Processing quality 0,00% (0)
	Plausibility unclear	0,00% (0)		
Target value not met			0,00% (0)	
Erroneous	Incorrect	0,00% (0)	100,00% (24)	
	Incomplete	100,00% (24)		

Processing remarks:

The respective entry or change "number / numerator / denominator" (dotted fields) is only possible in the spreadsheet "Basic data", carry-over is automatic.
The numerator is always a subset of the denominator (exception: Indicator 4 - Share of studies patients).

1) Plausibility unclear

In comparison to other centres, the indicator value given is an unusual value. The classification "plausibility unclear" does not automatically mean a negative assessment. The indicator value is to be checked for correctness because of its unusual character. In individual cases a positive indicator value, when viewed in detail, may also present a negative care situation (e.g. surplus care). The result of this check is to be explained in more detail by the Centre in the Catalogue of Requirements in the column "Reasons/Cause". Where appropriate, specific actions should be defined and carried out in line with the procedure "Failure to meet the target value" for the purpose of improvement.

2) Target value not met

The relevant indicators are to be analysed. The result is to be documented in the indicator spreadsheet (IS). The document "Specifications Data Quality" contains more detailed information about this.

3) Incomplete

If any indicators have the status "incomplete", then they either to be supplied at a later stage or a clear statement is to be made about the possibility of future presentation ("incomplete indicators" always constitute a potential deviation).