

ROSE TRIAL

Appendix A: Clavein-Dindo

A Phase III Randomized Trial of Systematic Lymphadenectomy in Patients with Apparent Early Stage High-grade Epithelial Ovarian Cancer

Protocol ID: ROSE | Protocol Version 5.0 | Appendix Version 3.0 | 01 September 2026

Purpose: The Clavien-Dindo classification will be used for standardized grading of postoperative complications in the ROSE trial. The classification will be applied to complications occurring after surgery, as specified in the study protocol. The modified definitions developed a priori for the ROSE trial should be used where applicable.

Grade	
1	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic and radiological interventions. Acceptable therapeutic regimens are: drugs as antiemetics, antipyretics, analgetics, diuretics and electrolytes and physiotherapy. This grade also includes wound infections opened at the bedside.
2	Requiring pharmacological treatment with drugs other than such allowed for grade I complications. Blood transfusions, antibiotics and total parenteral nutrition are also included.
3	Requiring surgical, endoscopic or radiological intervention
3a	Intervention under regional/local anesthesia
3b	Intervention under general anesthesia
4	Life-threatening complication requiring intensive care/intensive care unit management
4a	Single organ dysfunction
4b	Multi-organ dysfunction
5	Patient demise

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Appendix B – GCLQ-7 – Lymphedema-Specific Questionnaire

A Phase III Randomized Trial of Systematic Lymphadenectomy in Patients with Apparent Early Stage High-grade Epithelial Ovarian Cancer

Protocol ID: ROSE | Protocol Version 5.0 | PROM Appendix Version 3.0 | 01 September 2026

Instructions: Please answer each question based on your symptoms at the time of assessment.

No.	Question	Yes	No
1	Have you experienced limited movement of your knee ?	☐	☐
2	Have you experienced swelling ?	☐	☐
3	Have you experienced redness ?	☐	☐
4	Have you experienced firmness or tightness ?	☐	☐
5	Have you experienced swelling in the groin ?	☐	☐
6	Have you experienced heaviness in your limb(s)?	☐	☐
7	Have you experienced aching in your limb(s)?	☐	☐

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Appendix C – PATIENT-REPORTED OUTCOME MEASURES (PROMs)

A Phase III Randomized Trial of Systematic Lymphadenectomy in Patients with Apparent Early Stage High-grade Epithelial Ovarian Cancer

Protocol ID: ROSE | Protocol Version 5.0 | PROM Appendix Version 3.0 | 01 September 2026

Purpose and Instructions

This appendix describes the patient-reported outcome assessment planned for the ROSE trial. PROMs are intended to capture patient-reported health-related quality of life, lymphedema-related symptoms, and patient-perceived recovery following surgery.

1. PROM Assessment Schedule

Instrument	Baseline (pre-op)	Day 30 post-op	Month 12 post-op
FACT-O	✓	✓	✓
GCLQ-7	✓	✓	✓
Global recovery (0–10)	—	✓	✓

2. Patient and Assessment Details

Study ID _____

Centre _____

Assessment date ____ / ____ / ____

Assessment time point ☐ Baseline ☐ Day 30 ☐ Month 12

Date of surgery ____ / ____ / ____

Language of questionnaire _____

3. FACT-O: Health-Related Quality of Life

FACT-O completed ☐ Yes ☐ No

FACT-O score / prespecified database entry _____

Any item missed ☐ No ☐ Yes

If yes, item number(s) _____

4. GCLQ-7: Lymphedema-Specific PROM

GCLQ-7 completed ☐ Yes ☐ No

GCLQ-7 total score _____

Any item missed ☐ No ☐ Yes

If yes, item number(s) _____

5. Global Patient-Reported Recovery

At Day 30 and Month 12, participants will rate their overall recovery using a 0–10 numerical rating.

“On a scale from 0 to 10, where 0 means ‘not recovered at all’ and 10 means ‘completely recovered’, how recovered do you feel today?”

Assessment date ____ / ____ / ____

Score ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6 ☐ 7 ☐ 8 ☐ 9 ☐ 10

6. Additional Patient-Reported Consequences

Item	Yes	No	Baseline/30 day Post op/12 months post op
Lower-limb swelling since surgery	☐	☐	_____
Use of compression garment	☐	☐	_____
Referral to physiotherapy/lymph edema service	☐	☐	_____
Hospital readmission since surgery	☐	☐	_____
Reoperation since surgery	☐	☐	_____
Persistent symptom requiring medical attention	☐	☐	_____

7. PROM Data Quality and Completion

Was the PROM completed independently by the participant? ☐ Yes ☐ No

If assisted, reason _____

PROM assessment completed ☐ Yes ☐ No

If not completed, reason ☐ Patient declined ☐ Patient unavailable ☐ Too unwell ☐

Language/communication difficulty ☐ Technical/logistical reason ☐ Lost to follow-up ☐

Other: _____

Was any item missed? ☐ No ☐ Yes

If yes, item number(s) _____

Participant comments _____

Investigator / authorised study staff comments _____

Date reviewed ____ / ____ / ____

Appendix D: SAE Reporting Form

A Phase III Randomized Trial of Systematic Lymphadenectomy in Patients with Apparent Early Stage
High-grade Epithelial Ovarian Cancer

Protocol ID: ROSE | Protocol Version 5.0 | Appendix Version 3.0 | 01 September 2026

Purpose: This form is intended for reporting serious adverse events (SAEs) occurring in participants enrolled in the ROSE trial. It is adapted for a surgical interventional trial and should be completed by the site investigator in accordance with the SAE definitions, reporting timelines and procedures specified in the protocol and applicable institutional, ethical and regulatory requirements.

1. Study and Participant Details

Details

Study ID/Participant ID _____
Participating Centre _____
Site Investigator _____
Age at event _____ years
Date of randomisation ____ / ____ / ____
Date of surgery ____ / ____ / ____
Randomised treatment arm ☐ Arm A – Systematic LNE ☐ Arm B – No systematic LNE

2. Report Type

Report type	☐ Initial ☐ Follow-up ☐ Final	Date of report	____ / ____ / ____
If follow-up/final	Date of initial report: ____ / ____ / ____	Previous report/reference no.	_____

3. Description of Serious Adverse Event

Date of onset	____ / ____ / ____ Time: _____	Location	☐ Ward ☐ ICU ☐ OT ☐ Clinic ☐ Home ☐ Other
Date of hospital admission	____ / ____ / ____ / ☐ Not applicable	Date of discharge	____ / ____ / ____ / ☐ Ongoing
Date investigator became aware: ____ / ____ / ____			

SAE diagnosis / concise description of event:

Relevant clinical findings, investigations and laboratory/imaging results:

4. Timing and Relationship to Trial Procedures

The SAE occurred during:

- ☐ Preoperative period
- ☐ Intraoperative period
- ☐ Postoperative period ≤30 days
- ☐ Postoperative period >30 days
- ☐ Adjuvant chemotherapy
- ☐ Follow-up / other protocol-defined period

Potentially related trial intervention/procedure:

- ☐ Systematic pelvic/para-aortic lymphadenectomy
- ☐ Surgical procedure other than lymphadenectomy
- ☐ Anaesthesia/perioperative care
- ☐ Study-related investigation/assessment
- ☐ Other: _____
- ☐ No identifiable trial-related procedure

5. Seriousness Criteria

Tick all applicable criteria:

- ☐ Death
- ☐ Life-threatening condition
- ☐ New or prolonged hospitalisation
- ☐ Persistent or significant disability/incapacity
- ☐ Other medically important condition requiring intervention to prevent a serious outcome

If other medically important condition, specify: _____

6. Severity

NCI-CTCAE Version 5.0, where applicable:

CTCAE term: _____ Grade: ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5

7. Investigator Assessment of Causality / Relatedness

Relationship to systematic lymphadenectomy (if applicable):

☐ Definitely related ☐ Probably related ☐ Possibly related ☐ Unlikely related ☐ Definitely unrelated ☐ Not applicable

Relationship to other trial-related procedure:

☐ Definitely related ☐ Probably related ☐ Possibly related ☐ Unlikely related ☐ Definitely unrelated ☐ Not applicable

Investigator's assessment and justification:

8. Management of SAE

Management/intervention provided:

- ☐ Medical treatment
- ☐ Blood transfusion
- ☐ ICU admission
- ☐ Reoperation
- ☐ Interventional procedure
- ☐ Prolonged hospitalisation
- ☐ Other: _____

Details of treatment/management:

9. Outcome

☐ Fatal ☐ Recovered/resolved ☐ Recovering/resolving ☐ Not recovered ☐ Recovered with sequelae ☐ Unknown

Date of resolution/recovery, if applicable: ____ / ____ / ____

Details of sequelae, if applicable:

10. Similar Events / Relevant History

Has a similar SAE occurred previously in this study?

☐ Yes ☐ No

If yes, provide details: _____

Relevant pre-existing medical conditions / relevant history:

Concomitant medications and relevant dates:

11. Trial Continuation and Follow-up

Was the participant continued in the trial?

☐ Yes ☐ No ☐ Not applicable

If no, provide reason: _____

Further follow-up required:

☐ No ☐ Yes

Follow-up plan/details:

12. Reporting and Communication

Reported to Local EC/IRB	☐ Yes ☐ No Date: ____/____/____	Reported to TMC-K EC/IRB	☐ Yes ☐ No Date: ____/____/____
Reported to Coordinating Centre	☐ Yes ☐ No Date: ____/____/____	Reported to DSMC	☐ Yes ☐ No Date: ____/____/____
Additional regulatory reporting	☐ Yes ☐ No	Protocol amendment potentially required	☐ Yes ☐ No

13. Compensation / Research-related Injury

If the SAE is determined to be related to research participation, document the medical management, assistance/compensation provided or planned, and the responsible payer in accordance with the approved protocol, insurance/indemnity arrangements and applicable ICMR/EC requirements.

Details:

14. Ethics Committee / IRB Assessment

EC/IRB assessment of relatedness to research:

☐ Related to research ☐ Not related to research ☐ Unable to determine

EC/IRB comments / recommendations:

Name/designation of EC representative	_____ —	Date	____/____/____
Signature	_____ —	EC Ref. / communication no.	_____ —

15. Investigator Certification

I certify that the information provided in this report is accurate and complete to the best of my knowledge and that the SAE has been assessed and reported in accordance with the ROSE trial protocol and applicable institutional, ethical and regulatory requirements.

Name of Investigator	_____	Designation	_____
Signature	_____	Date	____ / ____ / _____
Contact number/email	_____	Site	_____

Appendix E: CTCAE v5

A Phase III Randomized Trial of Systematic Lymphadenectomy in Patients with Apparent Early Stage High-grade Epithelial Ovarian Cancer

Protocol ID: ROSE | Protocol Version 5.0 | Appendix Version 3.0 | 01 September 2026

Purpose:

The National Cancer Institute Common Terminology Criteria for Adverse Events (NCI-CTCAE), Version 5.0, will be used for standardized grading of the severity of adverse events reported during the ROSE trial.

CTCAE grading version 5.0

Common Terminology Criteria for Adverse Events (CTCAE) v5.0

Publish Date: November 27, 2017

Introduction

The NCI Common Terminology Criteria for Adverse Events is a descriptive terminology which can be utilized for Adverse Event (AE) reporting. A grading (severity) scale is provided for each AE term.

SOC

System Organ Class (SOC), the highest level of the MedDRA¹ hierarchy, is identified by anatomical or physiological system, etiology, or purpose (e.g., SOC Investigations for laboratory test results). CTCAE terms are grouped by MedDRA Primary SOCs. Within each SOC, AEs are listed and accompanied by descriptions of severity (Grade).

CTCAE Terms

An Adverse Event (AE) is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medical treatment or procedure that may or may not be considered related to the medical treatment or procedure. An AE is a term that is a unique representation of a specific event used for medical documentation and scientific analyses. Each CTCAE v4.0 term is a MedDRA LLT (Lowest Level Term).

Grades

Grade refers to the severity of the AE. The CTCAE displays Grades 1 through 5 with unique clinical descriptions of severity for each AE based on this general guideline:

Grade 1 Mild; asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated.

Grade 2 Moderate; minimal, local or noninvasive intervention indicated; limiting age-appropriate instrumental ADL*.

Grade 3 Severe or medically significant but not immediately life-threatening; hospitalization or prolongation of hospitalization indicated; disabling; limiting self care ADL**.

Grade 4 Life-threatening consequences; urgent intervention indicated.

Grade 5 Death related to AE.

A Semi-colon indicates 'or' within the description of the grade.

A single dash (-) indicates a Grade is not available. Not all Grades are appropriate for all AEs.

Therefore, some AEs are listed with fewer than five options for Grade selection.

Grade 5

Grade 5 (Death) is not appropriate for some AEs and therefore is not an option.

Definitions

A brief Definition is provided to clarify the meaning of each AE term. A single dash (-) indicates a Definition is not available.

Navigational Notes

A Navigational Note is used to assist the reporter in choosing a correct AE. It may list other AEs that should be considered in addition to or in place of the AE in question. A single dash (-) indicates a Navigational Note has not been defined for the AE term.

Activities of Daily Living (ADL)

*Instrumental ADL refer to preparing meals, shopping for groceries or clothes, using the telephone, managing money, etc.

**Self care ADL refer to bathing, dressing and undressing, feeding self, using the toilet, taking medications, and not bedridden.