Title Page

Protocol Title: CARS-3

Brief title: From rotator cuff surgery to reverse shoulder arthroplasty – clinical outcomes and radiological results 10 years after surgery

A prospective cohort study to investigate clinical and radiological outcome with patient reported outcome measurements (PROMs) and x-ray in patients 10 years after undergoing arthroscopic rotator cuff repair for acute or degenerative rotator cuff tear.

Protocol Number: 2.0

Amendment Number: 2.0

Study Phase: Including

Regulatory Agency Identifier Number(s):

Clinicaltrials.gov:	
Regional Committees for Medical and Health Research Ethics (REK):	520047
Current Research Information System In Norway (CRISTIN):	2559577

Approval Date:

Principal investigator Signatory:

Kjersti Kaul Jenssen, MD, PhD	**Date 09.09.24**

Principal investigator functions including Medical Monitors, Coordinating Investigator, and Principal Investigator Names and Contact Information can be found in Appendix 10

Protocol Amendment Summary of Changes Table

DOCUMENT HISTORY	
Document	**Date**
2.0 Full protocol norcrin template	*09.09.2024*
1.0 Original Protocol "Prosjektbeskrivelse"	*01.11.2022*

Amendment 2.0 (09.09.2024)

This document is a synthesis of the project protocol submitted and approved by REK, along with local agreements and adjustments for the study. This document is therefore non substantial with regards to the trial, but relevant for the supervision of it (article 81.9)] based on the criteria set forth in Regulation 536/2014 of the European Parliament and the Council of the European Union. This is because it neither significantly impacts the safety or rights of the subjects or on the reliability and robustness of the data generated in the clinical trial.

Overall Rationale for the Amendment:

Minor changes to criteria. Constant Murley score and MRI results removed from secondary outcome as the results from patient reported outcome measurement and x-ray is sufficient to answer the research question. WORC Index set to primary outcome alone. More accurate description of statistical analysis.

Removed non-important/not applicable text from chapter 9 and 11. Updated index.

Section # and Name	**Description of Change**	**Brief Rationale**
3. Methods	Removal of MRI and Constant Murley score. WORC Index set to primary outcome alone.	Not necessary

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List of Abbreviations

AE	*Adverse Event*
SAE	*Serious Adverse Event]*
SA	*Shoulder arthroplasty*
RC	*Rotator Cuff*
aRCR	*Arthroscopic rotator cuff repair*
CA	*Cuff arthropathy*
RSA	*Reverse shoulder arthroplasty*

1. Protocol Summary

1.1. Synopsis

Protocol Title:

CARS-3

Brief Title:

From rotator cuff surgery to reverse shoulder arthroplasty – clinical outcomes and radiological results 10 years after surgery

Objectives, Endpoints, and Estimands:

Objectives	Endpoints
Primary	
• WORC Index	• Change baseline to 10 years postoperatively
Secondary	
• Cuff arthropathy	• Cuff arthropathy on x-ray according to Hamada-Fukuda and Seebauer Classification at 10 years postoperatively
• EuroQol-5 (EQ-5D-5L)	• Change in EQ-5D-5L from baseline to 10 years postoperatively.
• Subjective Shoulder Value	• SSV score 10 years postoperatively
• Rotator Cuff Survival	• Survival of RC repair in terms of number of RSA performed in the study group within 10 years postoperatively

Overall Design Synopsis:

This study is a cohort study design. All patients have already been operated.

Brief Summary:

The purpose of this study is to measure clinical and radiological results in participants with arthroscopic rotator cuff repair 10 years after surgery.

Study details include:

- The study duration will be up to 15 years postoperative (>10 years follow up in some patients as the study starts in 2024 and the patients are operated in the time period 2010-2014).
- The participants will be examined 10 years postoperatively and were examined preoperatively at the time of surgery in 2010-2014.

Number of Participants: 733

733 participants will be invited to participate in the 10-year follow up examination.

Data Monitoring/Other Committee: No

A data monitoring committee has not been appointed for this study.

1.2. Schedule of Activities (SoA)

- September 2024: Inclusion of patients starts
- 2024-2025: Data collection.
- 2026-2027: Statistical analyses and submission of manuscript to relevant journals.
- 2027-2028: Presentation of results from study 2 at relevant conferences.

2. Introduction

Shoulder pain is a common problem in the Norwegian population. Up to 34% of women and 28% of men on extended sick leave (>8 weeks) suffer from disorders of the shoulder, neck and upper extremity. Rotator cuff (RC) tear is a major cause of shoulder pain (1-3). RC lesions cause symptoms such as muscle weakness, pain and loss of shoulder range of motion. Arthroscopic RC repair is performed in an increasing proportion of these patients with increased results in shoulder function, but there is a lack in long term follow up (4-7). In this study we aim to evaluate pre- and perioperative prognostic factors for favorable outcome.

2.1. Study Rationale

2.2. Background

The incidence of RC tears is increasing, and so is the amount of arthroscopic RC repairs performed. Despite the reported good results, there is a large number of repairs that do not heal or re-tear. The high re-tear rate (10-25%) is a challenge and although several risk factors of re-tear have been suggested, more studies are required to identify the patients with risk of re-tear after surgery (4-10).

Patients with non-healed RC repairs or re-tears are at risk of developing osteoarthritis (OA) or a progressive massive tear leading to pain and dysfunction. There are few long-term follow up studies after RC repair. Development of OA to some degree is reported in as many as 55% of patients, some of whom need further surgery with a shoulder replacement (11-13). At the end stage of a RC tear, with muscle atrophy and fatty infiltration of the RC, joint replacement surgery with reversed shoulder arthroplasty (RSA) is a good treatment solution.

In this project, we address these critical gaps in knowledge and aim to investigate the factors influencing the clinical outcome after rotator cuff surgery and re-tear in a large prospective cohort study. We will study how many patients suffering from poor outcome and develop cuff arthropathy in need of RSA.

2.3. Benefit/Risk Assessment

We foresee no risks associated with completing this study, as there is no planned new intervention. We expect a high rate of patients who want to participate, as they were asked to do so when first joining the registry at the time of surgery. Complications will be registered.

2.3.1. Risk Assessment

The planned x-ray will not give any significant radiation dose and therefore we expect no risk of development of cancer, as described for large radiation doses.

2.3.2. Benefit Assessment

We expect that the benefit of the data and knowledge collected will be superior to the cost for the patients coming to a ten-year follow-up appointment

2.3.3. Overall Benefit Risk Conclusion

Considering the measures taken to minimize risk to participants participating in this study, the potential risks identified in association with this cohort study, where the intervention has taken place ten years ago, are justified by the anticipated benefits that may be afforded to participants with arthroscopic rotator cuff repair.

3. Objectives, Endpoints, and Estimands

Objectives	Endpoints
Primary	
• WORC Index	• Change from baseline to 10 years postoperatively
Secondary	
• Cuff arthropathy	• Cuff arthropathy on x-ray according to Hamada-Fukuda and Seebauer Classification at 10 years postoperatively
• EuroQol-5 (EQ-5D-5L)	• Change in EQ-5D-5L from baseline to 10 years postoperatively.
• Subjective Shoulder Value	• SSV score 10 years postoperatively
• Rotator Cuff Survival	• Survival of RC repair in terms of number of RSA performed in the study group within 10 years postoperatively

Primary estimand

The primary clinical question of interest is:

Is it possible to develop a prognostic prediction model for favorable outcome 10 years after arthroscopic rotator cuff repair?

The estimand is described by the following attributes:

- *Population:*

  Patients with rotator cuff tear
- *Endpoint:*

  Change from baseline to 10 years in WORC Index and development of cuff arthropathy

4. Study Design

4.1. Overall Design

Prospective cohort design of 733 participants.

4.2. Scientific Rationale for Study Design

The study design is well suited to follow many patients over time. They will be asked to submit their patient reported outcome measures digitally and they will be evaluated on x-ray. The validated chosen PROM (WORC Index) is reported to be correlated with clinical function evaluated by a physiotherapist (Constant Murley Score). With this design and choice of outcomes, we will be able to answer our research question.

4.3. End-of-Study Definition

The end of the study is defined as the date of the last x-ray or submission of PROMs of the last participant in the study.

A participant is considered to have completed the study if the participant has completed all periods of the study including the last x-ray and all of the PROMs.

5. Study Population

733 patients operated at Lovisenberg Diaconal Hospital for an arthroscopic rotator cuff repair in the period 2010-2014.

5.1. Inclusion Criteria

Participants are eligible to be included in the study only if all of the following criteria apply:

Age

1. Participant must be 18 to 95 years of age inclusive, at the time of signing the informed consent.

Type of Participant and Disease Characteristics

2. Participants who have been operated with an arthroscopic rotator cuff repair and included in the rotator cuff registry at Lovisenberg Diaconal Hospital 2010-2014.
3. Participants who are able to read and write Norwegian

Sex and Contraceptive/Barrier Requirements

4. All

Informed Consent

5. Capable of giving signed informed consent

5.2. Exclusion Criteria

Participants are excluded from the study if any of the following criteria apply:

Medical Conditions

1. Lack of competence to consent

Other Exclusion Criteria

2. Patient is unwilling or unable to participate
3. Not able to submit patient reported outcome measurements in any format and x-ray
4.

5.3. Screen Failures

A screen failure occurs when a participant who has consented to participate in the clinical study is not subsequently entered in the study. A minimal set of screen failure information is required to ensure transparent reporting of screen failure participants to meet the CONSORT publishing requirements and to respond to queries from regulatory authorities. Minimal information includes demography, screen failure details, eligibility criteria, and any severe adverse events (SAE).

Individuals who do not meet the criteria for participation in this study screen failure will not be rescreened.

6. Study Intervention(s) and Concomitant Therapy

Study interventions are all pre-specified, investigational and non-investigational medicinal products, medical devices and other interventions (e.g., surgical and behavioral) intended to be administered to the study participants during the study conduct. The surgical intervention was performed in 2010-2014 and there is no planned new intervention.

6.1. Study Intervention Administered

Table 1. Study Intervention Administered

Intervention Label	
Intervention Name	Arthroscopic rotator cuff repair
Type	Surgical procedure
Use	The standard arthroscopic rotator cuff repair was performed by a trained orthopedic surgeon. The number of involved and sutured tendons, surgery on the biceps tendon, supplemental resection of acromion and acromioclavicular joint was reported with other concomitant procedures as well.

6.2. Assignment to Study Intervention

The participants who meet the eligibility criteria and are willing to participate will give consent and submit the patient reported outcome measurements electronically. They have already been operated and there is no new intervention planned. Hence this is a 10-year follow-up of already included patients treated with rotator cuff repair.

7. Discontinuation of Study Intervention and Participant Discontinuation/Withdrawal

7.1. Participant Discontinuation/Withdrawal from the Study

- A participant may withdraw from the study at any time at the participant's own request for any reason (or without providing any reason).
- A participant may be withdrawn at any time at the discretion of the investigator for safety and behavioral reasons.
- At the time of discontinuing from the study, if possible, an early discontinuation visit should be conducted, as shown in the SoA. See SoA for data to be collected at the time of study discontinuation and follow-up and for any further evaluations that need to be completed.
- The participant will be permanently discontinued from the study intervention and the study at that time.
- If the participant withdraws consent for disclosure of future information, the sponsor may retain and continue to use any data collected before such a withdrawal of consent.

7.1.1. Discontinuation of radiological examinations

- If the participant is not able or willing to conduct the planned x-ray examination, he/she will be asked to partly participate in the study. He/she will be asked to submit PROMs questionnaires.

7.1.2. Discontinuation of questionnaire

- If the participant is not able or willing to submit PROMs electronically, he/she will be asked to submit by paper.
- If the participant is not able or willing to submit PROMs neither electronically nor by paper, he/she will be asked to submit by phone call.
- If the participant is not able or willing to submit PROMs in general, he/she will be asked to partly participate in the study. He/she will be invited to conduct the x-ray examination.

7.2. Lost to Follow up

A participant will be considered lost to follow-up if the participant repeatedly fails to return for x-ray examination and submitting the patient reported outcome measurements and is unable to be contacted by the study site.

The following actions must be taken if a participant fails to submit the patient reported outcome measurements or the x-ray examination:

- The site must attempt to contact the participant and reschedule the missed visit as soon as possible, counsel the participant on the importance of maintaining the assigned visit schedule, and ascertain whether the participant wishes to and/or should continue in the study.
- If the participant cannot get the x-ray at the local hospital, he/she will be invited to participate only with patient reported outcome measurements.
- If the participant cannot submit the patient reported outcome measurements electronically, he/she will be invited to answer the scheme on paper and will receive the paper by mail.
- Before a participant is deemed lost to follow-up, the investigator or designee must make every effort to regain contact with the participant (where possible, telephone calls, and if necessary, a certified letter to the participant's last known mailing address or local equivalent methods). These contact attempts should be documented in the participant's medical record.
- Should the participant continue to be unreachable, the participant will be considered to have withdrawn from the study.
- If vital status is determined as deceased, this will be documented, and the participant will not be considered lost to follow-up.

8. Study Assessments and Procedures

- Study procedures and their timing are summarized in the SoA. Protocol waivers or exemptions are not allowed.
- Adherence to the study design requirements, including those specified in the SoA, is essential and required for study conduct.
- All screening evaluations must be completed and reviewed to confirm that potential participants meet all eligibility criteria. The investigator will maintain a screening log to record details of all participants screened and to confirm eligibility or record reasons for screening failure, as applicable.
- Procedures conducted as part of the participant's routine clinical management and obtained before signing of the ICF may be utilized for screening or baseline purposes provided the procedures met the protocol-specified criteria and were performed within the timeframe defined in the SoA.
- In the event of a significant study-continuity issue (eg, caused by a pandemic), alternate strategies for participant visits, assessments, medication distribution and monitoring may be implemented by the sponsor or the investigator, as per local health authority/ethics requirements.

8.1. Administrative Procedures

8.2. Safety Assessments

Planned timepoints for all safety assessments are provided in the SoA.

8.2.1. Physical Examinations

- Preoperative physical examination was performed before the participant received the arthroscopic rotator cuff repair 2010-2014.
- No new physical examination is planned in this study.

8.2.2. Radiological Examinations

- Participants will be examined by x-ray of the shoulder in standard projections:
    - One scapular Y-view
    - Three in anteroposterior view with arm in neutral, 30° external rotation and 60° internal rotation

- Degree of cuff arthropathy will be described according to Hamada classification, grade 1-5.

8.2.3. Patient reported outcome measurements (PROMs)

Participants will be asked to submit PROMs.

- PROMs questionnaire will be sent out electronically and participants will be asked to submit electronically in the "Nettskjema" portal.
- PROMs planned for this study
  - Western Ontario Rotator Cuff Index (WORC). Disease specific questionnaire to measure health-related quality of life, validated in patients with rotator cuff disease. Original A. Kirkley, S. Griffin, CCD, C. Alvarez 1998. Norwegian version is cross-culturally adapted according to the guidelines for translation of outcome measures, by Ekeberg et al. 2008.
  - EQ-5D-5L. Generic quality of life questionnaire measuring health in five dimensions. Original fra EuroQol Group. Norwegian version 2011.
  - Subjective Shoulder Value (SSV). Participant's subjective shoulder assessment expressed as a percentage of an entirely normal shoulder, which would score 100%. Norwegian version.
  - Additional questions regarding reoperation, patients satisfaction and if they would have been willing to undergo the procedure again will be asked

8.3. Adverse Events (AEs) Serious Adverse Events (SAEs), and Other Safety Reporting

We foresee no adverse events or serious adverse events in completion of our study as there is no planned new intervention. We foresee no AE or SAE in relation to the PROMs being submitted. If any AE or SAE occur in relation to the planned x-ray examination, this will be reported in a separate form and in the electronic patient journal.

The investigator and any qualified designees are responsible for detecting, documenting, and recording events that meet the definition of an AE or SAE and remain responsible for following up. This includes events reported by the participant (or, when appropriate, by a caregiver, surrogate, or the participant's legally authorized representative).

8.3.1. Time Period and Frequency for Collecting AE and SAE Information

All SAEs will be collected from the start of study intervention (start of inclusion for the 10-year follow up) until the last follow-up visit.

All AEs will be collected from the start of study intervention (start of inclusion for the 10-year follow up) until the last follow-up visit.

Medical occurrences that begin before the start of study intervention (start of inclusion for the 10- year follow up) but after obtaining informed consent will be recorded as medical history/current medical conditions, not as AEs.

All SAEs will be recorded and reported to the sponsor or designee immediately and under no circumstance should this exceed 24 hours. The investigator will submit any updated SAE data to the sponsor within 24 hours of it being available.

Investigators are not obligated to actively seek information on AEs or SAEs after conclusion of the study participation. However, if the investigator learns of any SAE, including a death, at any time after a participant has been discharged from the study, and the investigator considers the event to be reasonably related to the study intervention or study participation, the investigator must promptly notify the sponsor.

8.3.2. Method of Detecting AEs and SAEs

Care will be taken not to introduce bias when detecting AEs and/or SAEs. Open-ended and nonleading verbal questioning of the participant is the preferred method to inquire about AE occurrences.

8.3.3. Follow-up of AEs and SAEs

After the initial AE/SAE report, the investigator is required to proactively follow each participant at subsequent visits/contacts. All SAEs will be followed until resolution, stabilization, the event is otherwise explained, or the participant is lost to follow-up (as defined in Section 7.3).

8.3.4. Regulatory Reporting Requirements for SAEs

- Prompt notification by the investigator to the sponsor of an SAE is essential so that legal obligations and ethical responsibilities towards the safety of participants and the safety of a study intervention under clinical investigation are met.
- The sponsor has a legal responsibility to notify both the local regulatory authority and other regulatory agencies about the safety of a study intervention under clinical investigation. The sponsor will comply with country-specific regulatory requirements relating to safety reporting to the regulatory authority, institutional review boards (IRBs)/independent ethics committees (IECs), and investigators.

9. Statistical Considerations

The statistical analysis plan will be finalized prior to inclusion of first participant. This section is a summary of the planned statistical analyses of the most important endpoints including primary and key secondary endpoints.

9.1. Statistical hypothesis

The main objective is to develop a prognostic prediction model for clinical outcome 10 years after arthroscopic rotator cuff repair. To quantify the relative importance of preoperative and perioperative prognostic factors on functional outcomes ten years after rotator cuff repair and to identify and quantify patients who need shoulder replacement surgery ten years after rotator cuff repair as a measure of failure.

9.2. Statistical Analyses

9.2.1. General Considerations

- Descriptive statistics will be provided as means with standard deviation (SD) and mean differences as two-sided 95% confidence intervals (CI).
- Significance level is set to 5%.

9.2.2. Primary Endpoint Analysis

9.2.2.1. WORC Index

- The analysis will be performed to develop a prognostic prediction model for favorable outcome after 10 years
- Minimal important change (MIC) is set to -275 points (of a total score of 2100). If calculated as prosentage MIC is set to 13 ((275/2100)*100).
- WORC Index at baseline, 1, 2 and at 10 years will be reported as total raw score (SD). Mean difference will be presented as whole number with 95% CI. Decrease or increase in WORC Index score will also be presented as percent.
- Prognostic factors will be used in a multivariable linear regression model with appropriate methods for variable selection. WORC Index at 10 years as dependent variable. Results will be provided as coefficients with 95% CI and P-value.

9.2.3. Secondary Endpoint Analysis

9.2.3.1. Cuff arthropathy on x-ray

- Descriptive statistics will be provided as means with standard deviation (SD).
- A suitable inter/intrarater reliability test (Gwets AC or Cohen's Kappa) will be performed on agreement of arthropathy degree in 50 x-ray images. This will be performed at time 0 and after 3 weeks.

9.2.3.2. EQ-5D-5L

- EQ-5D-5L at baseline and at 1, 2 and 10 years will be reported as a total score (SD). Mean difference will be presented as whole number with 95% CI.
- A paired sample t-test or statistical models for repeated measurements may be performed to evaluate change in continuous outcome across time.

9.2.3.3. Reverse shoulder arthroplasty and RC survival

- Survival of RC repair in terms of number of RSA performed in the study group within 10 years postoperatively
- Descriptive statistics will be provided as means with standard deviation (SD)

9.2.4. Other Analyses

9.3. Sample Size Determination

733 participants will be invited to participate. We do not expect 733 to be included as some of them is now old, some are not alive and some will not be willing, or able, to consent. The sample size calculation is done in STATA 18.0 and based on calculation of a sample size required for developing a clinical prediction model as described by Riley et al.

Adjusted R^2=0.36 as described by Jenssen et al. at the two year follow up of the same cohort. 25 variables are included. The mean preoperative WORC at inclusion is set as the intercept (44) and standard deviation is based on the intercept (18,3).

This gives us a sample size of 458 participants. The cohort is set from the start of the project in 2010, but we hope to include a minimum of 458 participants in this round and find the expected samples size adequate.

9.4. Appendix 1: Regulatory, Ethical, and Study Oversight Considerations

9.4.1. Regulatory and Ethical Considerations

- This study will be conducted in accordance with the protocol and with the following:
    - Consensus ethical principles derived from international guidelines including the Declaration of Helsinki and
- The study will utilize data from a prospective registry of all arthroscopic repaired RC tears performed at Lovisenberg 2010-2014.
- All patients included in the registry have received written and oral information and signed an informed consent for their registry data to be used for research.
- Qualitative data registries of treated patients do not require approval from the national or regional committees in Norway, and therefore MD, PhD Kaul-Jenssen received an exemption from the Regional Committee for Medical and Health Research Ethics, section South-East C, Norway (IRB00001870), allowing her project to be implemented without further approval. Results from the prospective registry of all arthroscopically repaired RCs with 2-year follow-up data were published in 2018 (46).
- We will now use these data and ask the same patients to join the ten-year follow-up. We received new approval from the Regional Committee for Medical and Health Research Ethics to implement this in December 2022 (ID: 520047).

9.4.2. Informed Consent Process

- The investigator or the investigator's representative will explain the nature of the study, including the risks and benefits, to the potential participant and answer all questions regarding the study.
- Potential participants must be informed that their participation is voluntary. They will be required to sign a statement of informed consent as approved by the Regional Committee for Medical and Health Research Ethics.
- The participant will sign the consent form electronically by using their personal Bank-ID for secure two-step verification.

9.4.3. Data Protection

- Participants will be assigned a unique identifier by the sponsor. Any participant records or datasets that are transferred to the sponsor will contain the identifier only; participant

names or any information which would make the participant identifiable will not be transferred.

- The participant must be informed that their personal study-related data will be used by the sponsor in accordance with local data protection law. The level of disclosure must also be explained to the participant who will be required to give consent for their data to be used as described in the informed consent
- The contract between sponsor and study sites specifies responsibilities of the parties related data protection, including handling of data security breaches and respective communication and cooperation of the parties.
- Information technology systems used to collect, process, and store study-related data are secured by technical and organizational security measures designed to protect such data against accidental or unlawful loss, alteration, or unauthorized disclosure or access.

9.4.4. Study and Site Start and Closure

First Act of Recruitment

The study start date is the date on which the study will start to invite participants to the 10-year follow up.

The first act of recruitment is the date of first invitation and will be the study start date.

Study/Site Termination

The sponsor or designee reserves the right to close the study site or terminate the study at any time for any reason at the sole discretion of the sponsor. Study sites will be closed upon study completion. A study site is considered closed when all required documents and study supplies have been collected and a study-site closure visit has been performed.

The investigator may initiate study-site closure at any time, provided there is reasonable cause and sufficient notice is given in advance of the intended termination.

Reasons for the early closure of a study site by the sponsor or investigator may include but are not limited to:

For study termination:

- Discontinuation of further study intervention development

For site termination:

- Failure of the investigator to comply with the protocol, the requirements of the IRB/IEC or local health authorities, the sponsor's procedures, or GCP guidelines
- Inadequate or no recruitment (evaluated after a reasonable amount of time) of participants by the investigator

- Total number of participants included earlier than expected

If the study is prematurely terminated or suspended, the sponsor shall promptly inform the investigators, the IECs/IRBs, the regulatory authorities, and any contract research organization(s) used in the study of the reason for termination or suspension, as specified by the applicable regulatory requirements. The investigator shall promptly inform the participant and should assure appropriate participant therapy and/or follow-up.

9.4.5. Publication Policy

- The results of this study may be published or presented at scientific meetings. If this is foreseen, the investigator agrees to submit all manuscripts or abstracts to the sponsor before submission. This allows the sponsor to protect proprietary information and to provide comments.
- The sponsor will comply with the requirements for publication of study results. In accordance with standard editorial and ethical practice, the sponsor will generally support publication of multicenter studies only in their entirety and not as individual site data. In this case, a coordinating investigator will be designated by mutual agreement.
- Authorship will be determined by mutual agreement and in line with International Committee of Medical Journal Editors authorship requirements.

9.5. Appendix 10: Contact details

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