CASCADE

CArdiovaSCulAr outcomes after major abDominal surgEry

REGIONAL LEAD INFORMATION PACK

STARSurg

euroSURG

European student research network

Partners

BJS SOCIETY

Sponsors

THE ROYAL COLLEGE OF SURGEONS OF EDINBURGH

About this pack

We plan to launch the study with a full-day online informational event on the 8th of January 2022. In this booklet, we present a summary of the study protocol and project timeline, outline the steps you need to take before the study launch, and provide general tips and tricks for managing this project.

Collaborative Partners

ItSURG Collaborative
Italy
www.itsurg.org
itsurg.group@gmail.com
Twitter: @it_surg

PTSurg Collaborative
Portugal
www.ptsurg.org
info@ptsurg.org
Twitter: @pt_surg

SIGMA Collaborative
Germany
www.SIGMA-studies.org
team@SIGMA-studies.org
Twitter: @sigmastudies

Contents

1. Protocol Summary 4

2. Project Timeline 5

3. Before Study:

   i. Publicise the project & recruit collaborators 6

   ii. Identify senior supervisors 7

   iii. Register CASCADE as an audit 8

   iv. Organise the mini-teams 9

4. Regional Leads Tips and Tricks 10

5. Further Information 11

Protocol Summary

Background

- Postoperative cardiovascular complications increasingly common after major non-cardiac surgery, associated with increased costs to health and rates of disability, morbidity and mortality.

Aim

- Audit compliance to pre-, intra- and postoperative audit standards in reducing the risk of postoperative cardiovascular complications
- Assess rates and factors associated with postoperative cardiovascular complications

Inclusion Criteria

- Any hospital across Europe performing major abdominal surgery
- *Patient inclusion criteria:*
    - Consecutive adult patients (≥18 years old) undergoing emergency or elective abdominal visceral resection, reversal of stoma, open vascular surgery, anterior abdominal wall hernia repair, or transplant surgery
    - Any operative approach (open, laparoscopic, robotic)

Data collection

- Five 2-week periods between January and April 2022
- Collected using an online web application (REDCap), a widely used and secure data capture service.

Outcomes:

- Primary outcome: Postoperative cardiovascular complications[1]
- Secondary outcome:
    - 30-day mortality
    - 30-day venous thromboembolism
    - 30-day Clavien-Dindo grade

Local Approvals

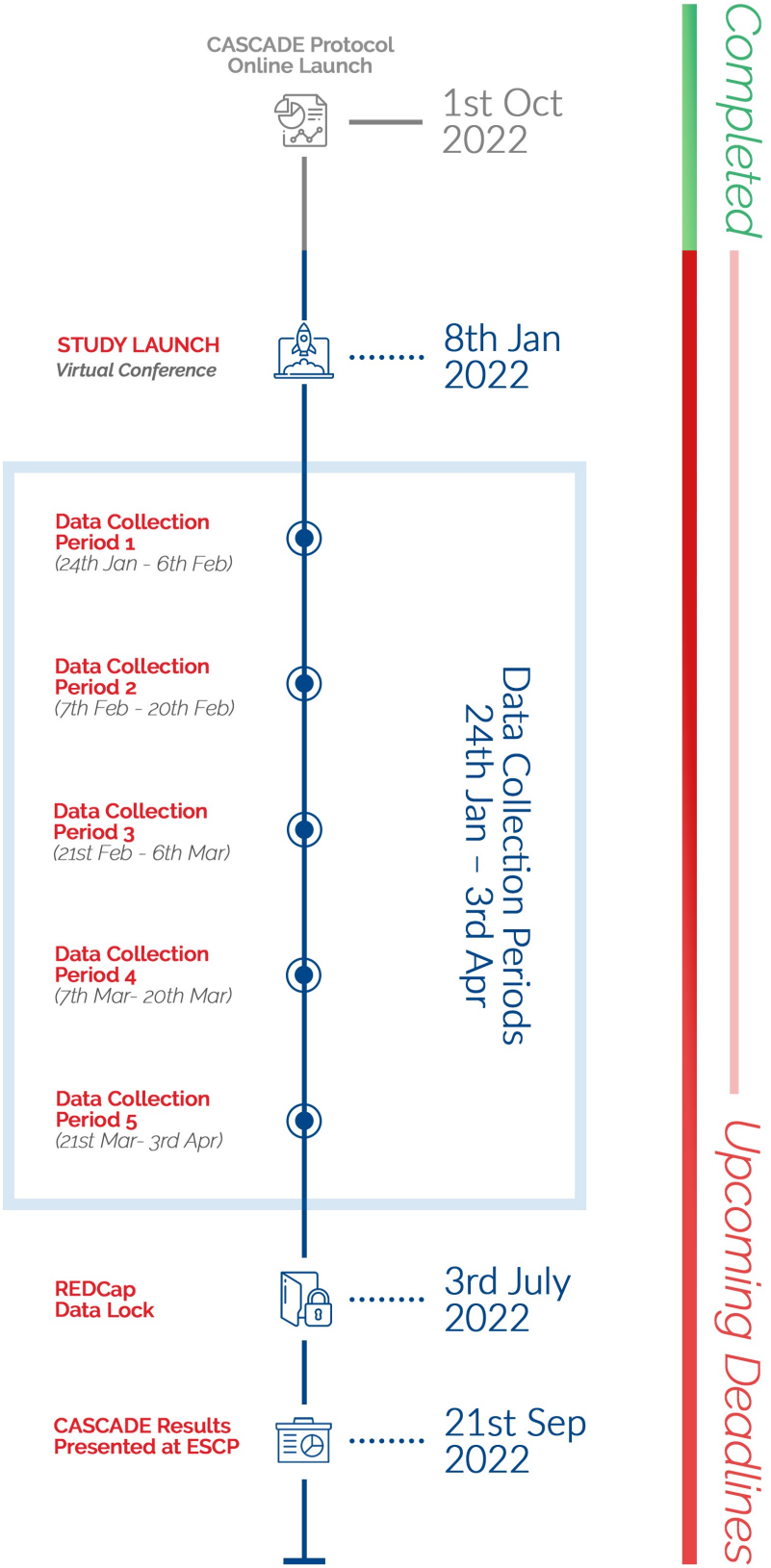
- Principal investigators at each participating site are responsible for obtaining necessary local approvals in line with hospital's regulations

Authorship:

- All collaborators will have PubMed-citable co-authorship on publications resulting from this study (https://starsurg.org/authorship-policy/)

Reference:
1. Beattie WS, Lalu M, Bocock M, et al. Systematic review and consensus definitions for the Standardized Endpoints in Perioperative Medicine (StEP) initiative: cardiovascular outcomes. Br J Anaesth. Jan 2021;126(1):56-66.

Project Timeline



Before the Study Launch

1. Publicise the project & recruit collaborators

Advertise the CASCADE study at your local medical school and affiliated hospitals as soon as possible.

- Gaining interest and momentum of the study early on will ensure maximum participation from students and junior doctors
- We have included a promotional poster with standardised promotional text to help you with this process.

Recommended approaches to publicise the project and recruit collaborators include:

- **Public announcements** - lectures, hospital/university meetings and events held by your local societies focusing on surgical interests
- **Posters** - social areas/break rooms/changing rooms
- **Social media** - such as creating a Facebook group or Twitter page or posting on already existing Facebook and other social media groups
- **Posts** - in student bulletins or medical society newsletters
- **Emails** - local surgical departments, individuals, societies and associations who may be interested in the project

Through your advertisements, you will gain good support from medical students and junior doctors interested in collaborating on this project. Amongst the collaborators you recruit, you will need to identify **hospital leads** who will assist you with day to day running of the study at your affiliated sites – we recommend these to be senior medical students who will be able to dedicate additional time to the study, on top of collecting data.

When collecting information about the expression of interest, ensure that you collect all the necessary details to contact the students (emails and phone numbers), as well as their availability with regards to which data collection periods that would be able to take part in and in which centres they would be placed at the time. This will allow you to create mini-teams (discussed later in this booklet) effectively.

The maximum number of collaborators you can recruit will depend on the number of centres that you will identify as eligible.

Before the Study Launch

2. Identify senior supervisors

In parallel to the recruitment of collaborators, you should begin to gather senior support for the study locally. We recommend that you **find a supportive trainee** (i.e. senior house officer or registrar) **and consultant** who will help in facilitating the study locally.

Role of the supervising consultant at each participating sites:

- **Assist with audit registration**
- **Provide overall support** to the study

Due to the interdisciplinary nature of CASCADE, the supervising consultant can be either a **surgeon or an anaesthetist.**

You may use your personal networks to identify potential supervising consultants or use the departmental intranet to find contact details of consultant surgeons/anaesthetists and contact them either by **approaching in person or contacting via email.**

You can also identify registrar-grade doctors, who will assist with running the study locally, who will help you with identifying the consultant. We have provided an email template below in a separate file to assist with this.

You may delegate this step to hospital leads, as they will be the main point of contact for the supervising consultants locally. If you struggle with finding supervising consultants, please contact the steering committee as we can provide you with contact details of consultants who have taken part in our previous projects; however, it is not guaranteed that they would be willing to participate again.

Identifying supervisors, speaking to them, and registering the study can take some time so it's important that you **identify supervisors (with the help of HLs, if needed) as soon as possible to give enough time to register the audit.**

Before the Study Launch

3. Register CASCADE as an audit

CASCADE should be registered in the UK, ROI, and Europe as a clinical audit in each of the participating centres

- This is a responsibility of the regional leads (with the help of hospital leads) at each site to identify a local consultant surgeon or anaesthetist to supervise the study locally and facilitate registration. The registration process generally involves contacting the local hospital audit department to get the hospital audit registration form.
- Confirmation that ethical review is not required for CASCADE within the UK is available in **Appendix F** of the protocol.
- Examples of audit registration forms can be found online at **http://starsurg.org/cascade-hub/.**

When registering CASCADE as a clinical audit, you should emphasise that:

- CASCADE is a national audit, and all data collected will measure current practice
- In keeping with audit quality improvement (QI) methodology, patient consent does not need to be obtained because patients inherently consent to QI measures when consenting to treatment
- No changes to normal patient pathways/treatment will be made

All CASCADE data will be collected and stored online through a secure server on the Research Electronic Data Capture (REDCap) web application. REDCap allows collaborators to enter and store data in a secure system. Collaborators will be given REDCap project login details, allowing secure data collection and storage on its database.

Collaborators in the UK should seek their trust's **Caldicott Guardian's** permission to submit data to the REDCap system

- **No data should be uploaded to REDCap prior to written approval from the Caldicott Guardian**
- All data should be handled in accordance with national and local data governance policies.

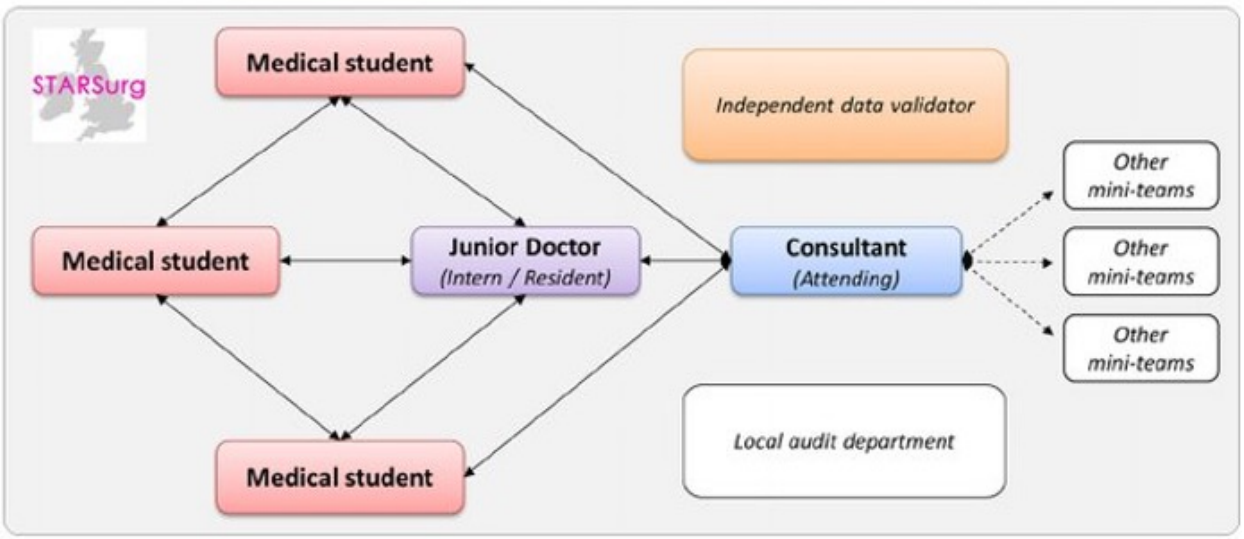
REDCap accounts will not be issued to your hospital leads until evidence is sent to us by you, on their behalf, that the following approvals are in place at their centre:

- Successful registration of CASCADE with the audit department
- Caldicott Guardian permission for data to be submitted to REDCap

Before the Study Launch

4. Organise the mini-teams

A team of up to 3 people is responsible for data collection per speciality group over a specific 2-week period at a particular centre. Ideally, this should be formed by 1-2 medical students collaborating with a junior doctor (FY1 to senior registrar grade). Reflecting the cross-speciality nature of the CASCADE audit, one mini-team (3 members) will be permitted per speciality group, defined as (1) gastrointestinal and liver surgery; (2) vascular and transplant surgery; (3) urological surgery; (4) gynaecological surgery (a maximum of 12 collaborators per data period per hospital).



Medical student
- Registers audit / research locally
- Identify patients for inclusion in study
- Data collection

Junior Doctor
(Intern/Resident)
- Supervises students
- Assists in registering audit/research
- Helps identify patients

Consultant *(Attending)*
- Clinical governance
- Overall responsibility for patient care
- Supervises junior doctor and students

Independent validator
- Validates data collected
- Work at selected data collection sites
- Reports to steering committee

The role of the FY1s and surgical trainees is to support medical students in the clinical environment and the role of the supporting consultant is to supervise and support local study registration. You should liaise with your hospital leads with regards to setting up your mini-teams. We will provide a template on how to organise mini-teams in your area.

Checklist Summary

	Completed?
1. Identify a list of potential participating centres associated with your university	☐
2. Recruit collaborators & publicise the study	☐
3. Appoint hospital leads from amongst collaborators	☐
4. Along with hospital leads, identify consultants and trainees to support audit registration process at each of the participating centres	☐
5. Register CASCADE as an audit at each of the participating centres	☐
6. Along with hospital leads, form mini-teams	☐
7. Register mini-teams on REDCap – to be explained at a later date	☐

Regional leads tips and tricks

- Make sure to **emphasise to each medical student their roles** and responsibilities upon signing up.

- Ensure **clear communication throughout**, including being welcome to questions being asked.
    - Collaborators should feel comfortable asking you anything regarding data collection.

- If the interest is greater than the maximum number of collaborators you can assign, you can **consider keeping a 'reserve' list**, should any of the collaborators be unable to participate due to an illness or other change in circumstance.

- Try to **have a varied level of seniority** of student collaborators within a mini-team
    - Where possible, it would be ideal to combine a student in clinical training with a pre-clinical student to maximise learning and teaching opportunities for them both.

- **Ensure handover between data collection is completed.**
    - This is critical for sharing any lessons learnt from period 1 into subsequent periods.

- **Frequently check in on collaborators** to open up discussion around any issues and look to encourage them to ask questions frequently on group chats to share information.

- Be organised and be prepared well in advance.
    - **Make sure deadlines are adhered to.**
    - **Keep track of collaborators and hospital leads,** their data collection periods and which hospital sites they're responsible for.

COVID Disruption

In the event COVID disrupts your placement:

- Follow local hospital/medical school guidance.
- If the number of hospital visits is limited, try to continue, as usual, bearing in mind the number of data collectors might be diminished.
- Work with junior doctors to divide the tasks evenly amongst yourselves.
- If students are not allowed on hospital premises, consider asking junior doctors and consultants to facilitate data collection going forward.

Further Information

Contact Details

We are here to help!

General queries: Regional leads or mini-team WhatsApp group chat
Dedicated CASCADE queries: cascade.audit@gmail.com
Dedicated REDCap queries: cascade.redcap@gmail.com

FAQ Meeting

We will be holding a **compulsory teleconference** to discuss any questions and concerns you may have regarding this whole process.

The meeting will be held on **15th of November 2021 at 7 pm** – the link will be shared via the WhatsApp group in due time.