

# A database to record safety information from patients who have had surgery using the Versius Surgical Robotic System

<b>Submission date</b> 11/09/2019	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/10/2019	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 26/01/2021	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

CMR Surgical, a medical device company based in Cambridge, UK, has designed and built Versius, a new surgical robotic system. Surgeons use Versius to complete a laparoscopic surgical procedure (keyhole surgery) by sitting at the surgeon console, next to the patient in the operating room but away from the operating table. The surgeon looks at a screen and uses hand controllers to control the surgical instruments. At the bedside, small, wheeled carts (bedside units) are positioned by the operating room staff. Each bedside unit holds a robotic arm which either holds a camera or surgical instrument for the procedure. This type of surgery, where surgeons and operating room teams interact with Versius to complete an operation is sometimes known as robotically assisted surgery.

To monitor how safe Versius is for patients, CMR surgical has launched a surgical registry (the CMR Surgical Registry). The registry will also provide a database of how surgeons are using Versius. The registry will collect important information about every operation a surgeon performs using Versius. For example, the information will include what operation was carried out, how long it took, and how the patient recovered afterwards. CMR Surgical is asking every hospital and surgeon who uses Versius to take part in the registry and collect information from every operation they carry out. The registry is important to CMR Surgical because the company takes its responsibility for patient safety very seriously. By law, surgical device companies must monitor the safety of devices such as Versius. The company also wants to use the information in the registry to help them make changes to Versius and how surgeons use it - these changes may benefit patients in the future. CMR Surgical also wants to support and promote academic research to make robot-assisted surgery even safer.

### Who can participate?

All patients eligible for surgery with Versius, as decided by the operating surgeon.

### What does the study involve?

All potential participants will have surgery as usual and as decided by their healthcare professionals. To participate, the patient must agree that their surgeon can provide information to the registry, including information collected relevant to the operation in their medical records.

What are the possible benefits and risks of participating?

There are no direct benefits to individual patients by participating in the registry. The information collected may benefit patients in the future. There are no risks to providing information to the registry. Surgical risks will be explained by the surgeon and will be the same whether the patient participates in the information collection or not..

Where is the study run from?

CMR Surgical (UK)

When is the study starting and how long is it expected to run for?

January 2019 to April 2025

Who is funding the study?

CMR Surgical (UK)

Who is the main contact?

Mark Slack, [registry@cmrsurgical.com](mailto:registry@cmrsurgical.com)

## Contact information

### Type(s)

Scientific

### Contact name

Dr Mark Slack

### ORCID ID

<http://orcid.org/0000-0003-2176-8118>

### Contact details

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Impington

Cambridge

United Kingdom

CB24 9NG

01223755300

[registry@cmrsurgical.com](mailto:registry@cmrsurgical.com)

## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

## Study information

### Scientific Title

CMR Surgical Registry

### Study objectives

Current study hypothesis as of 26/01/2021:

The registry will enable post-market surveillance and safety monitoring of the Versius Surgical Robotic System.

Previous study hypothesis:

The registry will enable post-market surveillance and safety monitoring of the Versius Surgical Robotic System, as well as record how surgeons use the system.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

The registry is a post-marketing surveillance database, collecting data about a new device used in routine clinical practice. It is not research and therefore does not require ethics approval.

### Study design

Prospective, observational, multi-centred registry

### Primary study design

Observational

### Secondary study design

Registry

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

See additional file (ISRCTN49651854\_PIS\_v5.0\_17Sep2019)

### Health condition(s) or problem(s) studied

Robot-assisted surgery, including urological, general, gynaecological, and thoracic laparoscopic surgical procedures

### Interventions

Current interventions as of 26/01/2021:

The Versius Surgical Robotic System is licensed for use in urologic surgical procedures, general laparoscopic surgical procedures, gynaecologic laparoscopic surgical procedures and thoracic laparoscopic surgical procedures. Peri-operative data will be collected from all consenting

patients undergoing an operation performed with Versius by their surgeon or surgical team. Data will be collected from patient medical records at the time of surgery and up to 90 days post-operative follow-up. The registry has been designed to collect information that is commonly recorded in the peri-operative environment for all surgical procedures.

**Previous interventions:**

The Versius Surgical Robotic System is licensed for use in urologic surgical procedures, general laparoscopic surgical procedures and gynaecologic laparoscopic surgical procedures. Peri-operative data will be collected from all consenting patients undergoing an operation performed with Versius by their surgeon or surgical team. Data will be collected from patient medical records at the time of surgery and up to 90 days post-operative follow-up. The registry has been designed to collect information that is commonly recorded in the peri-operative environment for all surgical procedures.

**Intervention Type**

Device

**Phase**

Not Applicable

**Primary outcome measure**

Intra- or post-operative complications recorded in the patient's medical records up to 90 days post-surgery

**Secondary outcome measures**

1. Rate of conversion to another surgical method identified during surgery
2. Operative time recorded during surgery as recorded in patient medical records
3. Length of hospital stay as measured as time from admission to date of discharge recorded in patient medical records
4. Return to OR within 24 h as recorded in patient medical records
5. Readmission to hospital within 30 days as recorded in patient medical records
6. 90-day mortality as recorded in patient medical records

**Overall study start date**

01/03/2019

**Completion date**

30/04/2025

## **Eligibility**

**Key inclusion criteria**

Any patient eligible for surgery using the Versius Surgical Robotic System as determined by their surgeon

**Participant type(s)**

Patient

**Age group**

Adult

**Sex**

Both

**Target number of participants**

All surgeries using Versius

**Key exclusion criteria**

Does not meet inclusion criteria

**Date of first enrolment**

02/03/2019

**Date of final enrolment**

31/01/2025

**Locations****Countries of recruitment**

England

France

India

Scotland

United Kingdom

**Study participating centre**

**Deenanath Mangeshkar Hospital & Research Centre**

c/o Dr Dhananjay Kelkar

Erandawne

Pune

Maharashtra

Pune

India

411004

**Study participating centre**

**HCG Manavata Cancer Centre**

Mumbai Naka

Nashik

India

422002

**Study participating centre**  
**Western General Hospital**  
NHS Lothian  
Edinburgh  
United Kingdom  
EH4 2XU

**Study participating centre**  
**Milton Keynes University Hospital**  
Milton Keynes University Hospital NHS Foundation Trust  
Milton Keynes  
United Kingdom  
MK6 5LD

## **Sponsor information**

**Organisation**  
CMR Surgical Limited

**Sponsor details**  
Evolution Business Park, Impington  
Cambridge  
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CB24 9NG  
01223755300  
registry@cmrsurgical.com

**Sponsor type**  
Industry

**Website**  
[www.cmrsurgical.com](http://www.cmrsurgical.com)

## **Funder(s)**

**Funder type**  
Industry

**Funder Name**  
CMR Surgical Ltd

# Results and Publications

## Publication and dissemination plan

CMR Surgical are committed to transparent communication of the analysis of registry data with planned publications in high-impact peer-reviewed journals. Where possible, cumulative analyses will be reported, with authors agreeing to abide by the International Committee of Medical Journal Editors (ICMJE) requirements.

## Intention to publish date

01/06/2026

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from [registry@cmrsurgical.com](mailto:registry@cmrsurgical.com). Data requests will only be accepted from academics, clinicians or research institutions and will be assessed by the Clinical and Medical Affairs Team and independent Registry Steering Committee. Persons wishing to submit a request to access a dataset from the registry must provide a detailed project plan explaining which data is requested and for what reasons. Data may only be released once further anonymised, grouped, and evidence of ethics permission obtained. Data request functions will only be available from 2020.

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	version v5.0	17/09/2019	08/10/2019	No	Yes