Study code: HRCC

Study title: The Hugo RAS Colorectal Collaborative (HRCC): An International Study to Advance Minimally Invasive Surgery

Author(s):	Prof Matteo Rottoli
	Dr Tommaso Violante

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PROTOCOL SIGNATURE PAGE

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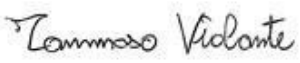
(Author *1*) Matteo Rottoli signature date



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(Author *2*) *Tommaso Violante* signature date

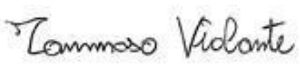
INVESTIGATOR'S STATEMENT:

Study code: HRCC

I declare that I have read the protocol and agree to conduct this clinical study in accordance with all the requirements of the protocol, the Good Clinical Practice guidelines and the Declaration of Helsinki principles.

30/08/2025

(Principal Investigator) *Matteo Rottoli* signature date



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(Co- Principal Investigator) *Tommaso Violante* signature date

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1 LIST OF ABBREVIATIONS

CRF	Case Report Form
GCP	Good Clinical Practice
BMI	Body Mass Index
HRCC	Hugo RAS Colorectal Collaborative
IBD	Inflammatory Bowel Disease
RAS	Robotic-Assisted Surgery (implied from Hugo RAS System)

2 Introduction

2.1 Background and study rationale

. Minimally invasive surgery is rapidly becoming the standard of care in colorectal surgery, with procedures like laparoscopy offering significant benefits to patients compared to open surgery(1). However, traditional laparoscopy has limitations, including reduced dexterity, challenging ergonomics for surgeons, and limitations in visualization (2). The Hugo Robotic-Assisted Surgery (RAS) system represents a significant advancement in robotic surgery, designed to overcome these challenges and further improve patient outcomes (3).

The Hugo RAS system offers several key features (4):

- Wristed Instruments: Enabling greater dexterity and range of motion, particularly crucial in complex colorectal procedures.
- Improved Ergonomics: Reducing surgeon fatigue and potentially enhancing precision, especially during prolonged operations.
- Enhanced 3D Visualization: Providing a more immersive and detailed view of the surgical field for improved decision-making.
- Modular Architecture: Allowing flexible configuration and customization to meet the specific needs of different surgical procedures and hospital environments, enhancing versatility and cost-effectiveness.

Early studies confirm the safety and effectiveness of the Hugo RAS system in colorectal surgery. However, long-term studies including oncologic outcomes analysis are still lacking (5). An international multicentre study, the Hugo RAS Colorectal Collaborative (HRCC), is proposed to provide necessary real-world evidence to address these knowledge gaps. This study will investigate patients undergoing colorectal surgery using the Hugo RAS system.

2.2 Importance of the study and its clinical relevance

The proposed "Hugo RAS Colorectal Collaborative" (HRCC) aims to analyse the short and long term outcomes of colorectal surgery performed by the use of Hugo RAS platform. The results of this study will contribute to highlight the effectiveness of robotic surgery in the treatment of various colorectal conditions, also using new platforms with a unique design such as the modular system of Hugo RAS. Furthermore, the study will contribute to the body of knowledge on robotic colorectal surgery and drive innovation in minimally invasive techniques. The registry will also provide data to support.

WHAT IS ALREADY KNOWN ON THIS TOPIC	Minimally invasive surgery is beneficial in colorectal surgery, but traditional laparoscopy has limitations The Hugo RAS system offers technological advancements like wristed instruments, improved ergonomics, and 3D visualization. Early studies on Hugo RAS clinical outcomes are limited, hindering widespread adoption
WHAT THE STUDY COULD ADD	Comprehensive real-world evidence on the short and long-term outcomes of the Hugo RAS system across a diverse range of colorectal procedures and patient populations. Data to inform best practices for robotic platform use, optimize patient care, and drive innovation in robotic colorectal surgery.

2.3 Is the study included in the research areas of IRCCS AOU Bologna?

Oncology	☒
Transplants and severe organ deficiencies	☐
COVID-19	☐
Other research area	☒

3 Aims and endpoints of the study

3.1 Primary aim(s)

The primary aim of this study is to analyse the short and long-term outcomes of patients undergoing colorectal surgery using the Hugo RAS system, by the mean of establishing an international dataset, the Hugo RAS Colorectal Collaborative (HRCC)

Secondary aim(s)

Secondary aims include:

- To compare specific clinical outcomes (e.g., recovery times, post-operative complications) among participating centers to identify surgical best practices.
- To foster the standardization of surgical techniques and setup procedures for colorectal surgery with the Hugo RAS system among participating centers.
- To evaluate the learning curve of surgeons using the system for this type of procedure.

3.2 Endpoints

Primary endpoint

Primary endpoint	How it will be measured	When it will be evaluated
• Short term outcomes of the Hugo RAS system	• Intraoperative complications (e.g., robotic arm conflicts, system alarms including red alarms, technical difficulties encountered); Postoperative complications (using Clavien-Dindo classification).	• Intraoperatively; Postoperatively (e.g., 30-day, 90-day)
• Efficacy of the Hugo RAS system	• Operative time, blood loss; Conversion rates to open or laparoscopic surgery; Length of hospital stay, readmission rates; Pathological outcomes (e.g., margin status, lymph node yield).	• Intraoperatively; Postoperatively; Upon pathology report

• Long-term outcomes after Hugo RAS assisted colorectal surgery	• Disease recurrence rates, survival data (overall and disease-free); Long-term functional outcomes (e.g., bowel function); Patient-reported quality of life.	• Long-term follow-up (e.g., 1 year, 3 years, post-surgery

Secondary endpoints

Secondary endpoints	***How it will be measured***	***When it will be evaluated***
Hugo RAS system utilization patterns	Data on system configuration (number of arms, specific instruments used), docking time, setup time, module usage; Frequency and reasons for alarms, technical difficulties.	Intraoperatively, collected for each procedure.
Data of robotic approach and docking of the robot	Analysis of system performance data, utilization of different settings, and user feedback (qualitative, if collected during collaborative meetings).	Periodically throughout the study, during data analysis phases.
Cost-effectiveness of Hugo RAS assisted colorectal surgery	Analysis of procedural costs, length of stay, complication-related costs, compared to potential benefits (specific metrics to be defined in cost-effectiveness analysis plan).	After sufficient data collection, planned for Year 3 analysis.
Standardization of techniques and collaborative learning	Documentation of shared practices; Feedback from participating centers; Adoption rates of any consensus guidelines developed through the collaborative.	Through periodic online meetings and updates; Ongoing throughout the registry.

4 Study plan

4.1 Type of study

RCT	☐
Non-randomized controlled study	☐
Experimental study, uncontrolled	☐
Cross-sectional study	☐
Retrospective Case-control study	☐
Retrospective cohort study	☐
Prospective cohort study	☒
Retrospective and prospective cohort study	
Clinical investigation with a CE-marked device used within its intended use, not conducted for conformity assessment purposes (Art. 82 of Regulation (EU) 2017/745).	☒☐

4.2 Mono- or multicentric study

Monocentric	☐
National Multicentric	☐
International Multicentric	☒

4.2.1 Coordination among centers

Coordination among participating centers will be managed by the principal investigator's institution. Key coordination activities will include:

- Providing standardized electronic data collection forms (eCRFs) developed in REDCap to all centers.
- Providing data dictionaries to all participating centers to ensure data standardization.
- Conducting regular audits to maintain data quality.
- Organizing periodic online meetings and updates to share analysis updates and key findings with participating centers. These meetings will also facilitate discussion and standardization of surgical techniques and setup procedures, and foster collaboration and knowledge exchange among surgeons and researchers.

4.3 Study design

This study is a prospective, observational, international, multicenter dataset of patients undergoing colorectal surgery using the Hugo RAS system. The aim is to collect comprehensive real-world data on the system's utilization and patient outcomes across a

diverse range of procedures and patient populations. Data will be collected via standardized electronic Case Report Forms (eCRFs). This is an observational study where patients will receive treatment (surgery with the Hugo RAS system) according to the standard clinical practice of the participating centers. Measures to reduce bias include:

- Standardized data collection using eCRFs in REDCap.
- Provision of data dictionaries to ensure data standardization across centers.
- Implementation of data quality control measures, including range checks, data validation rules, and regular data audits.
- Enrollment of all eligible patients undergoing Hugo RAS colorectal surgery at participating centers to minimize selection bias.

4.4 Study population

Participants will be adult patients (≥18 years) undergoing any type of colorectal surgery (elective or emergent) using the Hugo RAS system at participating high-volume colorectal surgery centers across multiple countries. The enrollment period will begin in Year 1 of the study, continue through Year 2, and potentially expand in Year 3, with ongoing long-term follow-up. Specific start and end dates for overall enrollment are yet to be defined and will depend on funding acquisition and ethical approvals. The coordinating center will be Alma Mater Studiorum - IRCCS Sant'Orsola-Malpighi Hospital, Bologna, Italy (Affiliation: IRCCS - Azienda Ospedaliero-Universitaria di Bologna Policlinico S. Orsola-Malpighi). Other participating UO/structures will be high-volume colorectal surgery centers recruited internationally. Participants will be identified and enrolled at the participating centers when they are scheduled for colorectal surgery to be performed with the Hugo RAS system.

4.4.1 Inclusion criteria

 Adult patients (age ≥18 years).
 Scheduled to undergo any type of colorectal surgery (elective or emergent) where the Hugo RAS system is planned to be used.

 Willing and able to provide written informed consent.

4.4.2 Exclusion criteria

 Patients unable to provide informed consent.

4.4.3 Study population size and statistical power

This study is designed as a clinical investigation aimed at collecting real-world data. Based on the case volume of the participating centers and the study duration, the target sample size is set at **2000** patients. This sample size is considered sufficient to provide descriptive data on safety and performance endpoints~~The total number of patients to be enrolled in the registry is not fixed with a formal sample size calculation, as this is a prospective observational registry aiming to collect comprehensive data from a diverse network of high-volume colorectal surgery centers (defined as performing at least 100 colorectal procedures per year). Enrollment will depend on the number of participating centers and their caseloads over the study period~~. The aim is to gather a substantial dataset to allow for meaningful analysis of efficacy, short and long-term outcomes. The number of patients to be recruited at the IRCCS Azienda Ospedaliero-Universitaria di Bologna will be ~~detailed in the center-specific module~~of 400 patients.

4.5 Intervention/treatment under investigation

The technology under investigation is the Hugo™ RAS (Robotic-Assisted Surgery) System, manufactured by Medtronic, used for performing colorectal surgical procedures. This is a medical device. The purpose of this study is to analyze the short- and long-term clinical outcomes in patients undergoing oncologic colorectal surgery performed with the Hugo™ RAS robotic surgery system.

The following information pertains to the Hugo RAS System:

- ™ RAS System. Manufacturer: Medtronic. (REF and specific supplier details to be added if required).
- **Risk Class:** To be added based on device documentation, typically Class IIb or III for robotic surgical systems).
- The Hugo RAS System console and arms are multi-use. Surgical instruments used with the system may be single-use or multi-use. Details of specific instruments used will be recorded.
- The Hugo RAS System is the primary apparatus. It consists of a surgeon console, robotic arms with instrument manipulators, and a vision cart.
- For any participating center where the Hugo RAS system is newly installed for the purpose of this registry or otherwise, compatibility verification by the respective hospital's Clinical Engineering service (or equivalent) will be ensured as per local institutional policy.
- The Hugo RAS System is intended for performing minimally invasive colorectal surgical procedures.
- The Hugo RAS System will be stored, prepared, and used according to the manufacturer's (Medtronic) instructions for use (IFU) and guidelines by trained surgical teams. Data on technical setup including docking time, system configuration, setup time, and module usage will be collected.
- Use of the Hugo RAS system requires specific training provided by the manufacturer (Medtronic) or certified trainers. Surgeons participating in the registry will be expected to have completed the required training and possess experience in minimally invasive colorectal surgery. The coordinating center (IRCCS - Azienda Ospedaliero-Universitaria di Bologna Policlinico S. Orsola-Malpighi) possesses experience with robotic surgery. The collaborative nature of the registry aims to facilitate discussion and standardization of surgical techniques and setup procedures.
- Not applicable, as the Hugo RAS system is a surgical tool operated by the surgical team and does not have direct patient management features or remote control by the patient.
    - It is currently already in use at IRCCS AOUBO
    - For other participating centers, the system may be already in use or will be acquired/provided according to their agreements. This registry does not directly fund the purchase of systems but collaborates with centers using Hugo RAS.

It is currently already in use at IRCCS AOUBO	☒
It will be provided on a free loan for use (multi-use DM)	☐
It will be provided free of charge by a third-party lender (single-use DM)	☐

4.6 Possible intervention/treatment control/comparison

This is an observational registry focused on the Hugo RAS system. There is no active control group assigned by the protocol. However, the statistical analysis plan includes "Comparative effectiveness analyses". These analyses may involve internal comparisons between different techniques or patient subgroups within the Hugo RAS cohort, or potentially comparisons with historical data or published literature on other surgical modalities (e.g., traditional laparoscopy, open surgery) for context, though these are not prospectively controlled comparisons.

4.7 Study duration

The total expected duration for the initial phase of the study (including primary data collection, analysis, and initial publications) is approximately 2 years, with long-term follow-up and data analysis continuing thereafter.

Phase of the study	Time (months/years)
enrollment/selection of patients	Year 1 (initiation), Year 2 (continuation), Year 3 (expansion). Estimated 24-36 months for primary enrollment.
treatment phase (if any)	Duration of surgery and hospitalization for each patient.
follow-up required for outcome assessment	Long-term follow-up data will be collected (e.g., up to 3 years or more post-surgery for outcomes like recurrence and survival)
data analysis	Initial analysis in Year 2; Further analyses (cost-effectiveness, long-term outcomes) in Year 3 and ongoing.
overall study duration	Approximately 3 years, followed by extended long-term follow-up and analysis.

4.8 Treatments, monitoring and evaluations

Data will be collected across the preoperative, intraoperative, postoperative, and long-term follow-up phases. Standardized electronic data collection forms (eCRFs) will be used.

4.8.1 First visit evaluations

Clinical history/current therapy ☒

Previous therapies ☒

Overall assessment ☒

Laboratory tests ☒

Outpatient visits and/or specialized examinations ☒

Administration of questionnaires ☐

Administration of scales ☐

Other ☐

(specify)

4.8.2 Evaluations at follow-up visits and timing

Laboratory tests ☒

Outpatient visits and/or specialized examinations ☒

Administration of questionnaires ☐

Administration of scales ☐

Other…….. ☐

(specify)

Type of evaluation	Description	Time of evaluation (days/months/years)	Is it within normal clinical practice or is it study-specific?	If already in clinical practice, is the timing different?
Intraoperative Data Collection	Technical setup, surgical procedure details, system performance (arm conflicts, alarms).	Intraoperatively	Study-specific detailed data capture of routine procedure elements.	No

Postoperative Complications	Assessed using Clavien-Dindo classification.	During hospital stay and up to 30/90 days post-discharge.	Normal clinical practice (assessment); study-specific (standardized recording using Clavien-Dindo).	No
Length of Hospital Stay, Readmission Rates	Data on discharge date and any readmissions.	At discharge; up to 30/90 days for early readmissions.	Normal clinical practice (data points); study-specific (systematic collection for registry).	No
Pathology Reports	Histopathology reports (tumor characteristics, margins, lymph node status).	When available post-surgery.	Normal clinical practice; study-specific (systematic collection of predefined data points).	No
Adjuvant Therapy	Details of chemotherapy, radiation therapy.	As applicable following surgery.	Normal clinical practice; study-specific (systematic collection for registry).	No
Long-Term Follow-Up (Recurrence, Survival)	Monitoring for disease recurrence, collection of survival data.	Annually or as per standard oncological follow-up (e.g., 6m, 1yr, then yearly up to 3yrs+).	Normal clinical practice (follow-up visits); study-specific (systematic data extraction for these endpoints).	No

Functional Outcomes & Quality of Life Questionnaires	Standardized questionnaires for bowel function, overall QoL. (given by the personnel of the surgical department)	Baseline, and e.g., 6 months, 1 year, 2 years, 3 years post-surgery.	May be study-specific if not part of routine follow-up at all centers, or if specific instruments are mandated.	Potentially, if frequency or instruments differ.

4.8.3 **Patient drop-out from the study**

4.9 Funding

Is funding provided for the study?

No	☐
Yes, from internal funds	☐
Yes, from institutional third parties	☐
Yes, from private third parties	☒

4.9.1 **Funding parties**

Covidien AG (Medtronic) will be supporting this study but will not be involved in any part of it. The purpose of the funding is to support the establishment and operation of the Hugo RAS Colorectal Collaborative (HRCC) international registry.

4.10 Data Management

The clinical data required by the protocol will be collected in pseudonymized form by personnel designated by the Principal Investigator in an electronic Data Collection Form (CRF) and will be managed through the REDCap platform. The eCRF in REDCap will be requested and implemented according to the procedure described in the "Corporate Operational Instruction for the Management and Use of the REDCap Platform" (IOA119). The Principal Investigator must indicate the names of personnel delegated to data management by specifying their relative functions within the study in the *Delegation log*.

4.11 Statistical Analysis Plan (SAP)

4.11.1 **Methodology of analysis**

The statistical analysis will use appropriate methods to address the study aims, including descriptive and inferential statistics. Comparative effectiveness analyses, survival analysis, regression modeling, and other appropriate statistical methods will be used to analyze the data. Specifically:

- **Descriptive statistics**: Frequencies, means, medians, standard deviations, and ranges will be used to summarize patient demographics, clinical characteristics, intraoperative variables (e.g., docking time, operative time, blood loss, system

configuration, alarms), and postoperative outcomes (e.g., length of stay, complication rates by Clavien-Dindo classification).

- **Comparative effectiveness analyses**: Will be performed to compare outcomes between different patient subgroups, procedural techniques, or system settings within the registry cohort.
- **Survival analysis**: Kaplan-Meier methods will be used to analyze time-to-event outcomes such as overall survival, disease-free survival, and time to recurrence. Cox proportional hazards regression modeling will be used to identify predictors of these outcomes, adjusting for potential confounders.
- **Regression modeling**: Logistic regression (for binary outcomes like complications) and linear regression (for continuous outcomes) will be used to explore relationships between patient/procedural factors and outcomes, and to control for confounding variables.
- **Subgroup analyses**: May be conducted based on type of surgical procedure, tumor stage, patient comorbidities, or other relevant factors to explore differential effects of the Hugo RAS system.
- **Management of missing data**: Appropriate methods for handling missing data (e.g., multiple imputation, sensitivity analyses based on different assumptions for missing data) will be considered and documented.
- **Sensitivity analyses**: May be conducted to assess the robustness of the findings to variations in analytical assumptions.
- **Cost-effectiveness analysis**: Specific methodologies will be applied to analyze data on cost-effectiveness as planned for Year 3.

4.11.2 **Risk factors, confounders and effect modifiers**

The following variables will be collected and considered in the analysis as potential exposures/risk factors, predictors, confounders, or effect modifiers:

- **Patient-related factors**:
  - Demographics: Age, sex, Body Mass Index (BMI), race/ethnicity, socioeconomic status (Data source: eCRF from patient records).
  - Medical History: Comorbidities (e.g., Charlson Comorbidity Index), previous abdominal surgeries, current medications (Data source: eCRF from patient records/interviews).
  - Indication for Surgery: Specific diagnosis (e.g., colorectal cancer, diverticulitis, IBD), underlying disease details (e.g., tumor stage – TNM, inflammation severity – e.g., endoscopic scores for IBD) (Data source: eCRF from pathology, imaging, clinical records). Diagnostic criteria will be based on standard international guidelines for each condition.
- **Procedure-related factors**:
  - Technical Setup: Docking time, system configuration (number of arms, specific instruments used), setup time, module usage (Data source: eCRF from surgical team input/operative log).
  - Surgical Procedure: Specific surgical techniques employed (e.g., type of resection, anastomosis technique, extent of lymph node dissection), use of advanced technologies (e.g., fluorescence imaging) (Data source: eCRF from operative log).
  - System Performance: Intraoperative conflicts of the robotic arms, occurrence and reason for alarms (including red alarms), any technical difficulties encountered (Data source: eCRF from surgical team input).

- **Center-related factors**: (e.g., center volume, surgeon experience with Hugo RAS – to be considered if data available).

4.11.3 Policy for sharing data with other researchers/research groups (data sharing)

Findings from the registry will be disseminated through peer-reviewed publications, conference presentations, and registry reports to participating centers. Periodic online meetings and updates will be provided to share analysis updates and key findings with participating centers. Requests for access to anonymized individual patient-level data by researchers external to the Hugo RAS Colorectal Collaborative (HRCC) steering committee will be considered on a case-by-case basis by the HRCC steering committee. A formal data sharing agreement outlining the terms of use, data security, and publication policies would be required. The primary aim is to protect patient confidentiality and ensure data is used responsibly for advancing scientific knowledge in line with the registry's objectives.

5 Administrative procedures and statements

5.1 Informed consent and consent to the processing of personal data

The study protocol, any amendments to the protocol, informed consent, consent to the processing of personal data and any other information for patients must be approved by the Ethics Committee.

To be included in the study, each patient must provide written informed consent as well as consent to the processing of his or her personal data.

5.1.1 Modalities for acquiring informed consent and consent to the processing of personal data

Trained medical personnel (e.g., surgeons, research nurses/coordinators) at each participating center will be responsible for providing patients with complete information about the study and for obtaining written informed consent and consent for data processing. Consents will typically be acquired at the outpatient colorectal surgery clinics or inpatient wards of the participating surgical units, prior to the surgical procedure.

5.1.2 Study phase during which consents will be obtained

Screening	☒
Baseline	☒
First follow-up visit	☒

5.2 Specific study Insurance

Due to the observational nature of the study, no study-specific insurance is stipulated.

5.3 Amendments to the protocol and changes in the conduction of the study

Any changes to the protocol will be made through an amendment, which will be submitted to the Ethics Committee. No other mode of amendment to the protocol is allowed during the study period. Any unexpected changes in the conduct of the study will be recorded in the "Clinical Study Report."

5.4 Publication of results

The investigator commits to:

- notify the conclusion of the study
- submit the study for publication to a peer-reviewed journal within 12 months of study completion and regardless of the nature of its results
- use the correct affiliation of our research institution (*IRCCS Azienda Ospedaliero-Universitaria di Bologna*) in the scientific publications that will be submitted,

For this purpose, the study will be registered on an Open Science platform (for example: osf.io, clinicaltrials.gov). Any formal submission or publication of data derived from this study shall be considered as a publication on behalf of the Investigator.

5.4.1 Strategies for the dissemination of results and for the reproducibility of research

Findings from the registry will be disseminated through multiple channels:

- **Peer-reviewed publications**: Targeting high-impact surgical and oncological journals. Initial findings are planned for publication starting Year 2, with subsequent papers on cost-effectiveness and long-term outcomes.
- **Conference presentations**: Presenting research at major national and international surgical conferences.

5.5 Storage of Documentation

The Investigator is responsible for the storage and preservation of the essential documents of the study, before, during the course of, and after the completion or interruption of the study, in accordance with the requirements of current regulations and GCP and corresponding timelines.

The data collected in the CRF will be in strictly pseudonymous form and the subject will only be identified with a number/code.

The Investigator shall keep the original patient data and the signed informed consent in a safe place to ensure that confidentiality and privacy are maintained.

5.6 Inspections/Audits

If a Regulatory Authority requests an inspection, the Investigator is required to inform the Ethics Committee immediately.

5.7 Contact Persons

The telephone numbers and e-mail addresses of the contact persons for the conduction of the study are listed in the Investigator Folder at the center.

6 Bibliography

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