Project partners

Project Owner

Project Owner	
Institution / company (Norwegian name)	AUGERE MEDICAL AS
Address	c/o OsloMet - storbyuniversiteSimula Metropolit...
Postal code	0130
City	OSLO
Country	Norway
E-mail	andreas@augere.md
Website	
Enterprise number	921501684
Is the Project Owner for this project defined as an undertaking according to the state aid rules?	Yes
Size of the enterprise	Small
Is the Project Owner part of the same business concern as any of the partners?	No
Partner's role	Both research activity and financing

Project administrator

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Last name	Petlund
Date of birth	270774
National identity number	
Gender	Male
Position/title	CEO
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Confirmation	✓ The application has been approved by the Project Owner

Project manager

First name	Pia Helén
Last name	Smedsrud
Date of birth	231185
National identity number	*****
Gender	Female
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Address	Pilestredet 52
Postal code	0167
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Country	Norway
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Academic degree	MD
Preferred language	Bokmål
Phone	41105523
E-mail	pia@augere.md

Collaborating partners and R&D-suppliers

1

Institution/ company	SIMULA METROPOLITAN CENTER FOR DIGITAL ENGINEERING AS
Address	C/O Simula Research LaboratoryPostboks 134
Postal code	1325
City	LYSAKER
Country	Norway
Enterprise number	920203612
Contact person	Pål Halvorsen

Application number: ES690071 - Project number: 327927 - IPNÆRINGSLIV21
Innovation Project Innovation Project for the Industrial Sector
Improved AI for Colonoscopy with Clinical Evaluation

Contact tel.	
Contact e-mail	palh@simula.no
Partner's role	Only research activity
Is the partner for this project defined as an undertaking according to the state aid rules?	No

Project participants

First name	Last name	Institution/company
Pia Helén	Smedsrud	Augere Medical
Thomas de	Lange	Augere Medical / Sahlgrenska Universitetssjukhuset
Håvard Nygaard	Espeland	Augere Medical
Michael	Riegler	SimulaMet
Andreas	Petlund	Augere Medical
Pål	Halvorsen	SimulaMet

Project info

Project title

Project title	Improved AI for Colonoscopy with Clinical Evaluation

Primary and secondary objectives of the project

Main Objective:
To improve the performance and results of colonoscopy by reducing human variability.

Secondary objectives:
1) clinically evaluate Augere's polyp CADe technology in a prospective, randomized multi-center study as well as to further research and improve the computer aided diagnosis (CADx) technology; 2) collect more clinical data at hospitals to avoid patient population and endoscopist technique bias (we are currently working with OUS and Sahlgrenska) to improve model training, and labelling of this data; for the next generation product we will 3) develop models and methods that allow for improved benefit for patients, medical experts and hospital management such as visual and explainable polyp characterization; and 4) develop methods for automatic assessment of endoscopic performance to improve the physicians' technique and guide them to explore all areas of the colon.

Project summary

The gastrointestinal tract is vulnerable to some of the most common cancer cases. Early detection of lesions is essential for survival and treatment. Colonoscopy is a visual examination of the insides of the colon, using a flexible scope with a camera. The performing endoscopist operates the scope while simultaneously assessing the video stream on a screen. All assessments are performed live, and the videos are usually not stored or available for later

reassessments. In colonoscopic procedures, lesions are often overlooked, e.g., 20% of polyps (possible predecessors of colorectal cancer) are missed or incompletely removed. Large variations in detection rates between the endoscopist examiners are also observed with 36 - 65% for individuals. If a polyp should be removed or not is decided by the endoscopist based on her visual assessment of malignancy, and eligible polyps are removed immediately. At Augere, we have developed technology to automatically detect polyps using real-time video analysis run on AI technology based on years of basic research at Simula Research Laboratory. Significant barriers related to regulatory compliance, technology validation and market readiness have already been overcome, and Augere now has a straight path to CE-approval and market access for the product. However, additional research should still be done to clinically validate the technology in randomized controlled trials to demonstrate clinical real-world performance at different patient populations. In this project we propose to perform multiple RCTs to determine the clinical performance of our Computer Aided Detection (CADe) system. In addition we will research and develop the next generation product, adding Computer Aided Diagnosis (CADx) and explainable results and transparent AI principles to the product. The research in this project will release the potential of this innovation, and pave the way for the next generation of AI-based detection and characterization tools.

Outcomes and impacts

This project seeks to create next generation AI for colonoscopy. Clinical validation of the technology will attract investors, paving the way for Augere to reach the market with its superior CAD technology. Building on this foundation, Augere will be well prepared to launch future products for other endoscopic procedures. As the company grows, this will lead to increased employment, as well as increased competency on the field of AI in endoscopy for Augere and the surrounding research communities in Norway. Clinically validation of CAD systems based on explainability and transparency will increase clinicians' trust in such systems, and raise the academic acknowledgement of the partners. Improved diagnosis of CRC and better quality colonoscopies will save hundreds of millions in treatment expenses for society, but most importantly lead to thousands fewer CRC related deaths and better quality of life for the patients.

Placement

Funding scheme - supplementary info from applicant

Programme / activity	IPNÆRINGSLIV21
Application type	Innovation Project

Topic

Thematic Area	Topic
Industry and services	Health industry
Industry and services	ICT industry

Classification of scientific disciplines

Filter by subject field	Filter by subject	Discipline
Medisin og helsefag	Klinisk medisinske fag	Gasteroenterologi
Matematikk og	Informasions- og	Simulering, visualisering, signalbehandling,

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Filter by subject field	Filter by subject	Discipline
naturvitenskap	kommunikasjonsvitenskap	bildeanalyse

Other relevant programmes/ activities/projects	Aktive prosjekter i Augere Medical: NFR/Nærings-PhD -Pnr.: 298862 Innovasjon Norge/Ekstraordinært Innovasjonstilskudd - Ref.: 2020/526645
If applying for additional funding, specify project number	
Is this proposal related to other grant applications or ongoing projects allocated support from the Research Council and/or any other public funding scheme?	No

Progress plan

Project period

From date (dd.mm.yyyy)	01.05.2021
To date (dd.mm.yyyy)	30.04.2024

Main activities and milestones in the project period (year and quarter)

	Milestones throughout the project	Main activity / Category	From	Quarter	To	Quarter
1	WP1/T1.1-Pilot Polyp CADe Clinical Eval.	Industrial research	2021	2	2021	4
2	WP2/T2.3-Explainable AI for CAD	Industrial research	2021	2	2024	2
3	WP3/T3.1-Colonoscopy video data collection	Industrial research	2021	2	2022	2
4	WP2/T2.1-Improved diagnosis	Industrial research	2021	3	2024	2
5	WP2/T2.2-Colonoscopy Guidance System	Industrial research	2021	3	2023	2
6	M1:Pilot polyp detection study completed	Milestone	2021	4	2021	4
7	WP3/T3.2-Annotation of clinical dataset	Industrial research	2022	1	2022	4
8	M2:Multicenter colonoscopy data collected	Milestone	2022	2	2022	2
9	WP1/T1.2-Multi Center Clinical Study	Industrial research	2022	3	2023	4
10	M3:Colonoscopy data annotated (dep: M2)	Milestone	2022	4	2022	4
11	M4:Prototype CADx and XAI ready for in-silic	Milestone	2022	4	2022	4
12	WP1/T1.3-In Silico Diagnostic Study	Industrial research	2023	1	2023	4
13	M5:Technology for guidance system complete	Milestone	2023	2	2023	2
14	M6:Multi-center RCT study complete	Milestone	2023	4	2023	4
15	M7:In-silico diagnostic study complete (dep:	Milestone	2023	4	2023	4
16	M8:Technology for guidance and XAI complete	Milestone	2024	2	2024	2

Budget

Costs per project partner per main activity (NOK 1000)

The heading of the table displays the activity numbers for main activities as these are listed in the Progress plan (when they have been entered). The selected category appears in parentheses.

	1 (IF)	2 (IF)	3 (IF)	4 (IF)	5 (IF)	7 (IF)	9 (IF)	12 (IF)	Sum
AUGERE MEDICAL AS	1398	2034	1398	2034	1398	1144	2161	1144	12711
SIMULA METROPOLITAN CENTER FOR DIGITAL ENGINEERING AS	219	1138	219	1095	1051	219	220	219	4380
Totals	1617	3172	1617	3129	2449	1363	2381	1363	17091

Cost plan (NOK 1000)

	2021	2022	2023	2024	2025	2026	2027	2028	Sum
Payroll and indirect expenses	3199	4172	3176	795					11342
Procurement of R&D services	937	1444	1485	513					4379
Equipment	200	100	50	0					350
Other operating expenses	285	285	300	150					1020
Totals	4621	6001	5011	1458	0	0	0	0	17091

Specification

Payroll and indirect expenses:
Internal personnel will be active at the collaboration clinics, designing and supervising the data collection and clinical trials. Technical Infrastructure and logistics pertaining to data collection is also handled by Augere personnel. The project is heavier in cost in the beginning of the project than towards the end, as prototype development and clinical trial set up is cost intensive. In addition, the data collection and pilot study will have a cost with the clinical providers.

Other operating expenses include direct costs pertaining to data collection, pilot study and clinical trials that will require internal hospital personnel to be present to handle the collection and anonymisation of patient data.
In addition, this post covers travels that include presence at academic and industry venues to present research results, build Key Opinion Leader network and recruit candidate clinics for clinical trials.

Equipment needed for the execution of data collection and clinical trials are included as follows:
- Hardware for effectively training and experimenting with models: 100 000
- Special computers and recording equipment for data collection in the clinics: 200 000
- Custom network storage device for keeping clinical data: 50 000

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Cost code (NOK 1000)

	2021	2022	2023	2024	2025	2026	2027	2028	Sum
Trade and industry	3499	4372	3326	845					12042
Research institutes	937	1444	1485	513					4379
Universities and university colleges									0
Other sectors	185	185	200	100					670
Abroad									0
Totals	4621	6001	5011	1458	0	0	0	0	17091

Funding by project partner (NOK 1000)

	The Research Council	Own financing	Other funding	Sum	Specification of other funding
AUGERE MEDICAL AS	5126	11965		17091	
Totalsum	5126	11965	0	17091	

Funding plan (NOK 1000)

	2021	2022	2023	2024	2025	2026	2027	2028	Sum
Own financing	1386	1800	1503	437					5126
International funding									0
Public funding		0							0
Private funding									0
The Research Council	3235	4201	3508	1021					11965
Totals	4621	6001	5011	1458	0	0	0	0	17091

Specification

Fellowship

Type of fellowship	From date (dd.mm.yyyy)	To date (dd.mm.yyyy)
Post-doctoral research fellowship	01.05.2021	30.04.2024

Attachments

Project description

Project description	ES690071_001_1_Prosjektbeskrivelse_20210415
Reference	Innovasjonsprosjekt i næringslivet 2021.pdf

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Curriculum vitae (CV)

Curriculum vitae (CV)	ES690071_002_1_CV_20210415
Reference	2021-april-CV-PH-ipn-medical.pdf

Curriculum vitae (CV)	ES690071_002_2_CV_20210415
Reference	2021-cv-HNE-ipn.pdf

Curriculum vitae (CV)	ES690071_002_3_CV_20210415
Reference	2021-CV-MAR-ipn.pdf

Curriculum vitae (CV)	ES690071_002_4_CV_20210415
Reference	2021-cv-PHS-ipn.docx.pdf

Curriculum vitae (CV)	ES690071_002_5_CV_20210415
Reference	2021-cv-TDL-ipn.pdf

Partner information

Partner information	ES690071_017_1_Bedriftsopplysninger_20210415
Reference	ipn-information-about-applicant-AUGERE-2021.pdf

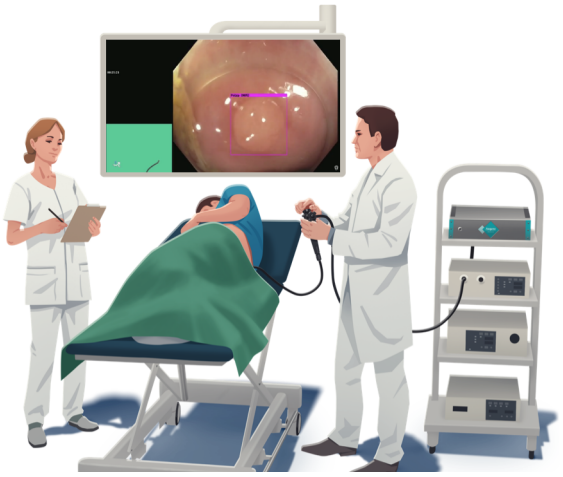
Partner information	ES690071_017_2_Bedriftsopplysninger_20210415
Reference	ipn-information-about-applicant-SIMULAMET-2021.pdf

Improved AI for Colonoscopy with Clinical Evaluation (CAD-Clinical)

PART 1: The planned innovation

1. Underlying idea

The human gastrointestinal (GI) tract can be the host for very common cancer cases. Early detection of lesions is essential for survival and less invasive treatment. Colonoscopy a visual examination of the insides of the large bowel, using a flexible scope with a camera and a light source on the tip. The performing endoscopist operates the scope while assessing simultaneously the video stream on a screen. All assessments are performed live, and the videos are usually not stored or available for later reassessments. In colonoscopic procedures, lesions are often overlooked, e.g., 20% of polyps (possible predecessors of colorectal cancer (CRC)) are missed or incompletely removed[3]. Large variations in detection rates between endoscopists are observed varying with 36-65%[4]. The endoscopists' decision whether a polyp should be removed or not is based on visual assessment of the lesions surface, and the polyp is removed immediately. Thus, the risk of getting cancer largely depends on the endoscopists' ability to detect, assess and remove relevant polyps.

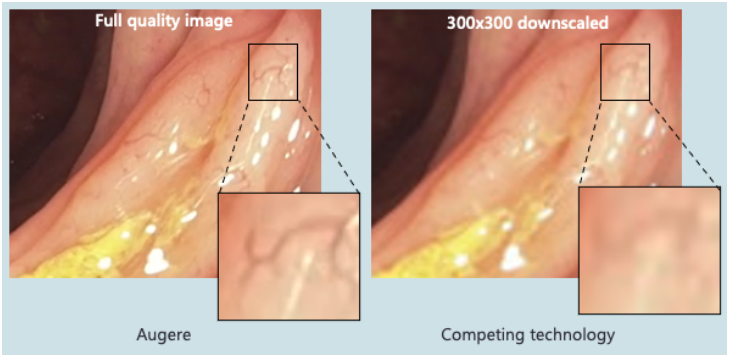


At Augere, we have developed technology to automatically detect polyps using real-time video analysis based on years of basic research at Simula Research Laboratory / SimulaMet and technology validation in the FORNY project GIRD (project 296520, 2019-2020), done in collaboration with Oslo University Hospital (OUS). Significant barriers related to regulatory compliance, technology validation and market readiness have already been overcome and Augere has a straight path to CE-approval and market access for the product. However, additional research is needed to clinically validate the technology in randomized controlled trials (RCT) to demonstrate clinical real-world performance at different patient populations. We raised 7.1 MNOK cash in April 2021 from Norwegian investors to partly fund this study, regulatory compliance activities and product development / design transfer readiness. In this project we propose to perform multiple RCTs to determine the clinical performance of our Computer Aided Detection (CADe) system. In addition, we also need to research and develop the next generation product going beyond simple automatic detection support and providing Computer Aided Diagnosis (CADx) and explainable results (this is important for patients, medical experts, law and hospital management). To achieve this we plan to research and integrate explainable AI (XAI) methods and transparent AI principles. Market research, health-economic models and interaction with Key Opinion Leaders agree that there is a need and huge market for tools that can reduce the human variability in colonoscopy but at the same time provide explainable results and transparency. Augere's technology solves central issues that enable a higher clinical relevance, as it can detect especially hard-to-find lesions, not adequately handled by competing products and state-of-the-art research. Our financial models show a potential profit of 100 million NOK/year in the EU and US markets after the first five years of sales. The research described in this proposal will be a key enabler to release the potential of this innovation, and pave the way for the next generation of AI-based detection and characterization tools that in the future also can be expanded to other medical fields with similar problems.

2. Level of innovation

As a result of this project, Augere will bring to the market both a new product related to CADx automatic diagnosis and clinical research that will lead to an improved product for CADe polyp detection. With the advent of deep learning technologies there has been an explosion of new applications where AI can aid or in some cases even replace human operators. The many overlooked polyps in colonoscopies documented in the literature is a prime candidate for AI enhancements. Simula has been a research leader in this field from the beginning and founded Augere Medical in 2018. At that time, no commercial solutions existed, and the

company found that the state-of-the art technology for object detectors in real-time had several shortcomings that limits the clinical relevance of the technology. Deep learning techniques such as object detectors used by competitors downscale images from HD to approx 300x300 to achieve real-time performance. This works well for large and fairly visible polyps as presented on the screen, but fails to detect flat and serrated polyps that require analyzing subtle details of the video including capillary structures. The technology developed in Augere overcomes several of these shortcomings, and represents a new generation product in the segment. We have developed in the FORNY-project and filed a patent [26] for key technology that extracts the most salient features using traditional computer vision techniques and combines this with deep learning and time series to enable detection of this often overlooked type of polyps, in addition to the more common and easier to detect polyps. The activities planned in this project will document the effect of the polyp detection technology in use in hospitals on real patients and bridge the gap between preclinical systems and how they can be efficiently transferred into clinical practice. This is an important step towards reaching the European and US markets, and will also document the value of the technology and company to potential investors as Augere prepares for sales upon reaching regulatory approval in the relevant markets. The XAI and diagnostic capabilities proposed in this project are new in the market and will build trust and help acceptance for technology in a conservative field by providing interpretability and explanations.



3. Potential for value creation

AI-assisted polyp detection is an emerging field with a huge market potential. We have estimated the EU and US market size to exceed 7 billion NOK/year based on health-economic research by Helseøkonomisk Analyse AS, market research by Ipsos, relative cost related to the price of a colonoscopy and price level for the first related products on the market. Even with conservative estimates for market penetration, the profit is expected to exceed 100 million NOK/year after the first 5 years of sales in the EU and the US, according to our financial models. To reach these markets, Augere needs to provide increasing levels of clinical documentation, showing Key Opinion Leaders and purchasers the value of the product. These first clinical results are therefore of critical importance for market readiness once the regulatory approval is in place. The R&D funding will thus be a stepping stone to reach a new level of growth for Augere, and also de-risk the project for future investors.

Regulatory compliance activities are performed in collaboration with our contract manufacturer Innokas Medical, and we expect to reach a CE mark in class 2a under MDR in 2022/2023. After this, a larger set of multi-centre clinical trials will be performed in the EU and the US to document the approved product for market purposes, enabling sale in larger volumes. This will require new investments in the size of 80-100 million NOK. Overall, the potential earnings of the market, based on the financial models, documents a huge opportunity. This next stage will bring the company to break-even and establish the company as a major international actor within real-time CADe/CADx services.

4. Project participants and constellation of partners

4.1 Research-performing and financing partners

4.1.1 Companies in Norway that will be using the R&D results in their own value creation

Augere Medical (AM) is a technology startup founded in 2018. The company's first product is a decision support tool for improving detection of lesions during colonoscopies. The company's technology is based on more than ten years of research from Simula in the field of AI in medicine (internationally they are one of the leading players in the field of AI for GI endoscopy). The technology delivered by Augere has been validated, partially through a RCN "FORNY" project, which has laid the ground for an in-silico trial that documents the technology for regulatory approval in the EU. Augere has just completed a financing round

where 7 million NOK of private capital has been invested in the company to partially finance the first hospital clinical trials of the technology. The first product is expected to be approved and released on the European market within the next 2 years. The Augere team has a unique combination of skills within clinical research, real-time processing, computer vision, and machine learning (ML), essential to be the leading provider of next generation real-time decision support tools for health applications.

4.1.2 R&D providers

The Holistic Systems Department (HOST) at SimulaMet investigates resource utilization and performance in complete, high-performance distributed systems, for machine learning applications in health. In a collaboration with Augere, researchers from HOST have contributed with cutting edge research within the fields of real-time anomaly detection, transparent AI systems, XAI and detection of especially challenging anomalies for medical scenarios. SimulaMet will be responsible for supervision of the research and providing assistance in designing candidate models for clinical trials, XAI frameworks, developing the transparent AI systems and interpreting the results.

4.2 Other forms of collaboration

The research project plans to perform data collection and clinical trials in collaboration with clinical partners in Norway, Sweden. In Norway, Oslo University Hospital (Ullevål, Rikshospitalet) will be our main collaboration partner, in Sweden will collaborate with Sahlgrenska Universitetssjukhuset and Karolinska Institutet. We already have established collaborations with these partners through the recently completed FORNY project, and they are ready to begin collaborations on the planned clinical trials. We will, through this project, also work to recruit a German clinical partner for clinical trials, as this is important to our product launch strategy.

PART 2: The R&D activities

5. Need for research

The proposed project targets an important medical scenario where nearly 2 million new cases of CRC are detected yearly in the world, resulting in about 1 million deaths [5]. All have a significant impact on a patient's quality of life. CRC is the third most common cause of cancer mortality for both women and men. Early detection is important for survival, i.e., going from a low 10-30% 5-year survival probability if detected in later stages (III-IV) to a high 90% survival probability in early stages (I-II)[6]. Colonoscopy is considered to be the gold standard for the examination of the large bowel for early detection of cancer and precancerous pathology. However, according to tandem studies where two doctors examined the same patient, 22% of the polyps were missed on average[6]. Further, the link between a colonoscopy examiner's detection rate and the risk of cancer is very clear, with a 3% decrease in the risk of cancer for each 1% increase in the ADR[7]. Colonoscopy is a demanding procedure that requires significant time and resources from the medical professional, leading to high costs related to the procedure. Norway has an average cost of about $450 per examination. In the US, colonoscopy is the most expensive cancer screening process, with an annual cost of $10 billion dollars nationwide, an average of $1,100 per examination.

From the AI perspective there is also an emergent need for further research. AI systems that can be used for clinical practice need to be transparent and explainable. Current systems mainly focus on visual or number based feedback and are not able to explain their decision or more importantly understand when they failed and learn from this. There are several parts in an AI pipeline that are important to avoid ending up with a useless not generalizable and reliable model[18,19], including knowledge about data distribution, model training and analysis result explanation. In the medical community a common understanding has emerged that clearly calls for explainable and transparent AI systems for clinical practice[20]. Current XAI methods can enable this to a certain extent but a better understanding of their implications and usefulness for the medical field needs to be researched.

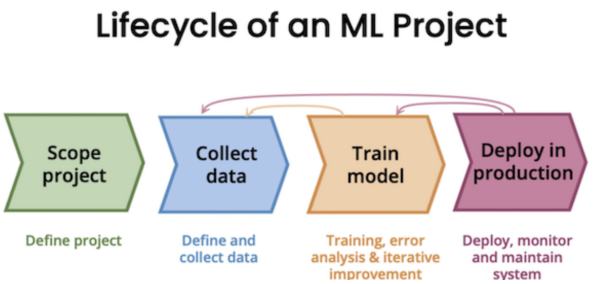
6. Objectives

The main objective of this project is to improve the quality and performance colonoscopy by reducing the substantial human variability in endoscopy. Several issues must be addressed to achieve this; 1) clinically evaluate Augere's polyp CADe technology in a randomized multi-center trial as well as to further research and improve the computer aided diagnosis (CADx) technology; 2) collect more clinical data at hospitals to

avoid patient population and endoscopist technique bias (we are currently working with OUS, Sahlgrenska and Ersta) to improve model training, and labelling of this data; for the next generation product we will 3) develop models and methods that allow for improved benefit for patients, medical experts and hospital management such as visual and explainable polyp characterization; and 4) develop methods for automatic assessment of endoscopic performance to improve the physicians' technique and guide them to explore all areas of the colon.

7. R&D challenges and scientific methods

Both academic researchers and commercial interests are currently focusing on ML to improve colonoscopy outcomes. There are several areas of research with regards to disease detection and classification, endoscopist performance evaluation, and usability of AI in clinical settings that are unsolved. In this project, we will address key R&D challenges directly exploitable for helping patients. ML methods and models are developed and evaluated iteratively in close collaboration with Simula.



7.1 Developing and validating systems for polyp detection and characterization

The foundation of a clinically useful AI system dependent on different components (model performance and analysis performance are most studied) but also training and validation data are crucial. Highly accurate AI systems trained on little and not diverse data from one center might not generalise well to previously unseen data [14], where generalisability has been directly connected to usefulness in clinical practice [22]. For Augere's further R&D there is a need not only for larger amounts of data [27], but also diversity of the data with regards to patient population, technical equipment and endoscopists. It is important that the data collection is tailored for the task the AI is meant to solve. For colonoscopy, this affects the patient population, the quality of the videos, choosing metadata, and how the data are managed. After collection, data needs to be annotated in order for algorithms to be able to make sense of it, meaning transferring information about the examination to the corresponding parts and findings in the colonoscopy videos. This is tedious and meticulous work, and it is important that the margin of error is kept at a minimum. Augere has previously developed a designated annotation software, which we will use to annotate both existing and new data for new applications.

Computer-aided detection (CADe) for polyp detection in colonoscopy significantly increases the detection of colorectal neoplasias, particularly the overall adenoma detection rate (ADR)[2]. However, these studies have not shown an increase in the detection of advanced adenomas, the most relevant precursors of (CRC) [15]. In addition, the results of these systems are not explainable and often hard to interpret. Augere's CADe system will be ready for clinical evaluation within summer 2021, and is developed based on high-quality data with focus on hard-to-find polyps and low false positive rate. The plan is to validate the system in two steps; one small-scale single-center clinical pilot study with focus on usability and technical validation, and a larger, multi-center, randomized clinical trial with focus on clinical effect on detection of polyps.

Hypothesis: CADe system works well with existing colonoscopy systems and is able to find polyps. *Method:* 50 patients at OUS in a small pilot trial. *Expected results and risks:* CADe system is usable and finds polyps. There is a risk that technical connections or video analysis fails.

Hypothesis: Increased polyp detection rate in a clinical setting with real patients. *Method:* 400 patients examined with CADe in a multi-center, randomized controlled trial. *Expected results and risks:* Increased polyp detection rate, including hard to find sessile serrated polyps. There is a risk that the trial finds that the system does not perform as well in real-life as in lab conditions.

AI algorithms characterizing colon polyps potentially predict the microscopic characterization, e.g., neoplastic or non-neoplastic, and thus predict the final diagnosis. Such systems are called CADx systems. Polyp CADx can help the endoscopist decide whether to remove the polyp or not during colonoscopy and therefore save time and money. Several small, unreliable single center studies on CADx systems have been conducted[17],. For these more fine grained analysis explainability and interpretability are even more important since the differences need to be clear and the decision to not remove a polyp should only be

done if the AI system has a high confidence. The American Society for Gastrointestinal Endoscopy have also developed diagnostic performance thresholds for endoscopic technology to minimize the risk of wrong diagnosis, with requirements equal to that of the highly trained gastroenterologists [21].

Hypothesis: Polyp characterization using an AI model classifier can provide patient benefit and cost reduction by avoiding removal of benign polyps. *Method:* Develop models for characterization and evaluate them on histology data collected in the dataset. *Expected results and risks:* We expect to achieve a high quality classification. There is a risk that the classification is not good enough, and we will evaluate this in an in-silico trial.

7.2 Colonoscopy guidance system

Guidance systems are another valuable application of AI in colonoscopy and can help the endoscopist achieve adequate inspection of the colon, e.g., by facilitating better bowel cleaning, mucosal coverage, tip control and adequate withdrawal time. A clean bowel is important for the performance of a high-quality colonoscopy [16]. Longer withdrawal time improves the ADR and thus reduces risk of cancer later on[1]. A study on an automatic quality control system, recording withdrawal time, scope stability, and bowel preparation in addition to polyp detection, showed prolonged withdrawal time and improved bowel preparation compared to controls [7]. There has also been research for developing algorithms to compute the coverage of a colonoscopy examination [8]. Augere seeks to improve these features, which in time may also play an important part in endoscopists education.

Hypothesis: A colonoscopic guidance system can be developed to improve the technique and coverage, and thus the performance of performing physicians. *Method:* Develop a real-time tool to aid and assess the technique used during a procedure and present this to the user. *Expected results and risks:* An guidance tool is developed. However, there is a risk that the users don't want to be instructed or assessed.

7.3 Development of explainable AI in a clinical setting

In the medical domain, making life-changing decisions without the ability to justify them, is unacceptable to both clinicians and patients. Thus, it is necessary to be able to explain how the algorithms made a particular decision, and there are strong requirements regarding trustworthiness of and trust in the use of the AI models, especially important for polyp characterization (CADx), in contrast to polyp detection. If a polyp is misdiagnosed as benign by the system and not removed, there is a harm to the patient. Developing a system presenting why the model makes the prediction and its certainty will be essential to gain uptake for CADx diagnosis in colonoscopy [9]. In case of high uncertainty, for example, more extensive tests can be performed. This does, however, require ML models to be equipped with uncertainty quantification abilities. Another significant challenge posed by many ML methods, is their tendency to be complex and opaque. This makes it impossible for clinicians to understand the logic underlying the predictions. A popular direct approach in academic research is visualizing the inner layers of the network to infer the emergent decision process. Heat maps are a common way to visualise the decision behind the classification of images. The resulting interpretation is thus an explanation for the decision as well as a representation of the system's own architecture. This concept leans on decomposability; while the entire system may be too complex to interpret, parts of it can be represented in a human-understandable way. For example, the system Mimir developed by Augere and SRL uses heat- and saliency-maps [10, 11]. This system aims to assist doctors in writing high quality medical reports of endoscopic examination of gastrointestinal diseases [12].

Hypothesis: In a computer aided diagnosis system, explaining to the physicians how the decision was made is key to build trust and must be done. *Method:* We will research and evaluate different ways to present characterization and their uncertainty to the physicians. *Expected results and risks:* We expect to be able to present reasonable explanations for the decisions. There is a risk that even with explanations, the predictions do not give enough trust for clinical value.

8. Project plan

8a) Main activities ("work packages") under the project

Work package number	1	Duration	Month 1 - 32
Work package title	Clinical Evaluation		
Participants	AM, SimulaMet	Leader	Pia Smedsrud, AM
Objectives	Evaluate technology in operational environment		

Task 1.1 Pilot Polyp CADe Clinical Evaluation - Task lead: AM, Milestone 1 (H2-21)
First test of developed colonoscopy polyp CADe algorithm in a real-life clinical setting. This will qualitatively test the system's ability to detect polyps without too many false positive alerts, and thus help endoscopists discover more polyps during colonoscopies in an efficient manner. This can validate the technical functionality with regards to real-time video analysis, usability, and user interface. Results from this study will be based on the participating doctors' experience and outcome of the examinations. Feedback from this study will also be valuable input for task 2.3 in WP 2.

Task 1.2: Multi Center Clinical Study of Polyp CADe Objective Performance - Task lead: AM, Milestone 6 (H2-23)
An international, multicentre clinical study of colonoscopy polyp CADe with the goal of increasing mean adenoma per patient (MAP) and adenoma detection rate (ADR) across different populations. The study will be designed as a randomized control trial comparing colonoscopies using our polyp CADe system to colonoscopies without CADe assistance. Main endpoint will be MAP. This study will potentially go into a FDA approval of the CADe system.

Task 1.3: In Silico Diagnostic Study - Task lead: AM, Milestone 7 (H2-23), Dependency: Milestone 3 and 4
In silico testing of the algorithms for polyp characterization developed in Task 2.1 in WP 2. The in silico study will include collecting of endoscopists performance which will serve as a baseline to which the algorithms performance will be compared.

Work package number	2	Duration	Month 1 - 36
Work package title	Next Generation Computer Aided Diagnosis		
Participants	AM, SimulaMet	Leader	Håvard Espeland, AM
Objectives	Research and develop technology for improved computer aid		

Task 2.1 Improved diagnosis - Task lead: AM, Milestone 4 (H2-22) and 8 (H2-24)
Research and develop algorithms for high quality polyp characterization. Such a system can help physicians to avoid costly biopsies and unnecessary resections to the patients. This CADx diagnosis is done from image analysis of regular light or white light colonoscopy. We will perform an in-silico study in T1.3 of the developed prototype technology and continue improving this throughout the project. Final evaluation in a RCT clinical trial is not part of this project.

Task 2.2: Colonoscopy Guidance System - Task lead: AM, Milestone 5 (H1-23)
In addition to aiding the physicians in detecting and diagnosing patients during a colonoscopy procedure, a major source of missed polyps in patients is the technique in operating the endoscope. We propose to develop an algorithm that continuously assesses the technique of the physician and the colon coverage observed. This assessment should be combined with an automatic estimation of the patient's bowel cleanliness. This is estimated by the physician today by the BBPS score, but is prone to subjective error.

Task 2.3: Explainable AI for CAD - Task lead: SRL, Milestone 4 (H2-22) and 8 (H2-24)
Enable physicians to improve trust in computer aided diagnosis and increase transparency of these systems by providing explanations to the decision makers. A major concern with computer aided diagnosis is that the computer's diagnosis is wrong. E.g., if the output of a characterization algorithm determines that a polyp is benign and should not be resected, there is real harm to the patient if this diagnosis is wrong. Physicians have real concerns related to this which is also represented in the endoscopic guidelines for colonoscopy. To establish a high level of trust in a computer diagnosis, a reliable system must be able to describe the reasons for deciding on a particular diagnosis in context to its AI pipeline components (e.g., it needs to take into account data distributions, used algorithms, etc. into the explanation). Thiswill enable the physicians to make the correct diagnosis, increase patient outcomes and help the hospital management to optimize processes.

Work package number	3	Duration	Month 1 - 20
Work package title	Data Collection and Annotation		
Participants	AM, SimulaMet	Leader	Håvard Espeland, AM
Objectives	Increase data quality to enable better AI performance		

Task 3.1 Colonoscopy video data collection - Task lead: AM, Milestone 2 (H1-22)
Multicenter data collection, with focus on high-quality data suitable for Task 2.1 and 2.2. This includes videos of entire colonoscopy examinations of relevant patient populations. This may include screening populations, and also referred patients. Metadata including pathology assessment of removed polyps and qualitative information about the examination will also be collected.

Task 3.2: Annotation of clinical dataset - Task lead: AM, Milestone 3 (H2-22), Dependency: Milestone 2
Further annotation of existing data and new data collected in Task 3.2. This will transfer information from the performing endoscopists and metadata from task 3.2 directly to findings in the videos. Labelling of the data will be related to both polyp detection and characterization, and features related to endoscopists guidance potentially increasing the quality of examinations.

8 b) Budgeted project costs distributed by main activity

No.	*Title of main activity / work package*	*Budgeted costs: (NOK 1000)*	*Costs: Industrial research*	*Costs: Experimental development*
WP1	Clinical Evaluation	6 836 421	6 836 421	
WP2	Research and develop technology for improved computer aided diagnosis	6 836 421	6 836 421	
WP3	Data collection and Annotation	3 418 211	3 418 211	
Total	***Entire project***	**17 091 053**	**17 091 053**	

8 c) Critical milestones for the R&D activities

Activity	H1-2021	H2-2021	H1-2022	H2-2022	H1-2023	H2-2023	H1-2024	
WP1: Task 1.1 - Pilot Polyp CADe Clinical Evaluation		M1						M1: Pilot polyp detection study completed
WP1: Task 1.2 - Multi Center Clinical Study of Polyp CADe...						M6		M2: Multicenter colonoscopy data collected
WP1: Task 1.3 - In Silico Diagnostic Study						M7		M3: Colonoscopy data annotated (dep: M2)
WP2: Task 2.1 - Improved diagnosis				M4			M8	M4: Prototype CADx and XAI ready for in-silico
WP2: Task 2.2 - Colonoscopy Guidance System					M5			M5: Technology for guidance system complete
WP2: Task 2.3 - Explainable AI for CAD				M4			M8	M6: Multi-center RCT study complete
WP3: Task 3.1 - Colonoscopy video data collection			M2					M7: In-silico diagnostic study complete (dep: M3, M4)
WP3:Task 3.2 - Annotation of clinical dataset				M3				M8: Technology for guidance and XAI complete

The milestones are listed in the figure above, with M1 being the most critical milestone that determines the first prospective clinical results in a pilot outside of our lab environment. Additionally, M4 represents the improved diagnosis CADx technology that will be developed in this project. Market acceptance in EU and FDA regulatory approval depends on positive results in M6 in a multi-centre clinical RCT and is critical.

8 d) Project organisation and management

The project will be governed by a Project Management Group consisting of the Work Package leaders, and the Primary Investigators from the R&D providers. The Management Group will convene quarterly to assess the progress of the project and, if needed, suggest corrective measures based on the performance. The Management Group will be supported by representatives from the clinical collaborators as needed, for advice on the state of the ongoing clinical data collection and trials. Augere will supervise and coordinate the research activities, while specific tasks will be managed by the R&D provider, SimulaMet. This is important to ensure the commercial elements of the planned work are constantly kept in sight as the project progresses.

The project manager, Pia Helén Smedsrud, was chosen due to the unique mix of technical and clinical skills and competence she possesses. As a Medical Doctor, she has a thorough understanding of the clinical aspects. She is also underway to complete a PhD in Computer Science, focusing on bridging the gap between technology and clinical knowledge in colonoscopy. She is therefore extremely well-placed coordinating this complex, cross-disciplinary project.

Partner	*Name of partner*	*Responsible for main activity:*	*Participating in the following main activities:*
C1	Augere Medical AS	WP1, WP2, WP3	WP1, WP2, WP3
R1	SimulaMet		WP1, WP2, WP3

Table 8 d) Distribution of tasks and responsibility in the project

9. Funding

Funding specification is provided in the grant application form.

PART 3: Plan for implementation and utilisation of results

10. Realisation of value creation for the Project Owner and partners

The research outlined in this proposal plays a critical role in two of Augere's main value drivers: 1) The launch of the company's first product - AI-based detection support for polyps and 2) Research on new services to later add to the product, including polyp characterization, bowel cleanliness rating and colonoscopy performance evaluation.

Augere expects regulatory approval of the detection tool to be in place late 2022 or early 2023. In anticipation of this key milestone, preparatory work will be done to make the organization ready for sales. Augere plans to provide direct sales in Germany and the Nordics, while securing distributor agreements for the rest of Europe. It will take several years to gain traction in the markets, since decision making processes

are slow in most hospital organizations. Working with Key Opinion Leaders in the target markets is one key activity that is critical to gain the trust needed to achieve sales in scale. This work ties closely into the recruitment of the right thought-leader clinics for the clinical trials outlined in this proposal, as well as later post-market studies.

In parallel with the preparation for direct sales, Augere will chart potential distributors for the different markets and initiate discussions on distribution agreements. Augere is in the process of recruiting a Business Developer that will, based on the results of the FORNY project, prepare the organisation for the upcoming sales and distribution activities. Also for this work, the results of the clinical trials will be very important to attract the best possible distribution partners.

Work has also been started to prepare for FDA approval for the first product. FDA approval is expected to be achieved in late 2023, upon which distributor negotiations for the US market must be well underway.

Activity	H1-2021	H2-2021	H1-2022	H2-2022	H1-2023	H2-2023	H1-2024	BM1: In-silico expert data collection complete
Regulatory (MDR + FDA)				BM4		BM6		BM2: Pilot clinical study shows expected results
In-silico trial	BM1		BM3					BM3: In-silico trial completed for use in CE approval
Pilot clinical evaluation		BM2						BM4: European regulatory approval achieved (MDR)
Larger clinical trial / post market						BM7		BM5: Organisation ready for sales in Europe
Business development (Distributor / sales org.)				BM5		BM8		BM6: US regulatory approval achieved (FDA)
								BM7: Post-approval multi-centre clinical trial successful
								BM8: Distributor agreements ready for sales in the US

The first CADe product in the segment (Medtronic GI-Genius) received CE mark in October 2019. Same as for Augere, Gi-Genius is a third-party device for the colonoscopic equipment. Currently there is a small set of early-stage systems available on the market. Among them systems from Olympus, Fujifilm and Pentax, the major colonoscopy equipment providers in the markets. Representatives of these actors openly communicate that the systems are first generation and that improvements must be expected. Early clinical trials also show that the systems are still lacking in detection of the hardest-to-find polyps. Augere's technology is centered around improving detection rate for such hard to detect polyps, and the core technology has been protected through a filed patent.

The patent was filed with PCT in June 2020 [26]. Search results with positive assessment were received, and the patent published in Dec. 2020. Final decision on which countries to enter in the national phase needs to be made by Dec 2021. Augere continuously assesses new technology elements for protection, and may file new patent candidates during the project period.

In order to reach the market, build a commercial organisation, finance the FDA process and reach break-even Augere plans to raise 100 million NOK over the next 3 years. The capital raise work has already begun in collaboration with a highly qualified Corporate Finance actor in France (Agile Capital Markets), having direct experience from the endoscopy business. An important part of the capital raise work and attracting the right investors for the commercial phase is to provide sound clinical data on the technology with increasing study size and trustworthiness. This work outlined in this research proposal aims to secure the stepping stones needed to close the needed investments for the commercial phase, effectively bringing the products to the market.

11. Socio-economic benefits and contribution to sustainable development in society

We do not expect any significant environmental impact related to sustainability from the activities in this project. The AI model and other software can be updated without replacing hardware allowing incremental improvement to the system as the research continues. The software runs on off-the-shelf hardware, and represents the estimated carbon footprint of a powerful computer workstation.

Considering the large fraction of missed polyps and large variation between endoscopist's performance, having a computer assisted diagnosis tool with real-time feedback during examinations to help increase the detection rate represents a significant benefit to society. Health economic models show that by placing 100 polyp detection aid devices into colonoscopy rooms, 600 lives can be saved, 1300 cancer cases prevented and 500 million NOK saved in treatment cost, over a period of 4 years. Most importantly, the technology allows for thousands of patients to enjoy many extra years of life in good health.

12. Dissemination and communication of results

Research outcomes will be actively broadcasted through popular-scientific publications/venues nationally and internationally, aiding in placing the company and its research on the map. The scientific results will

also be used in engagement with key opinion leaders and leading clinics in order to further the knowledge about quality in colonoscopy. This will also aid Augere in expanding its key opinion leader network and recruit thought-leaders as participants for clinical trials.

Technical findings will be published in peer-reviewed applied journals and conferences, including ACM MM, MMSys, ISM, ICME, NeurIPS and ICML, and also journals, like ACM TOMM, IEEE TMM, Nature Medicine and Nature Machine Intelligence. In the area of medicine, we target both tool-oriented medical conferences and publication venues including medical imaging, gastroenterology, hepatology, GI endoscopy, etc. Results will be disseminated to relevant medical projects, organizations and boards, including the Scandinavian Association for Digestive Endoscopy, the Norwegian Association of Gastroenterology, the European Society of Gastrointestinal Endoscopy, and the World Organization of Digestive Endoscopy. We will also attend national and international health tech conferences to disseminate the system, keep informed of the status of competition and to place Augere firmly on the industrial map of the sector.

All project outcomes that are not protected for business purposes will be disseminated through publications, lectures or as open source software.

PART 4: Other information

13. Ethical perspectives

When developing anomaly detection systems using AI, one need always be aware of biases that may affect the outcomes. This awareness is incorporated in every step of Augere's development process, from data collection to final product, and is continuously reviewed in order to ensure a balanced model. Even though we are not aware of any biases related to the inside of the large bowel, Augere strives to expand the datasets used to incorporate a steadily growing diversity of patients pertaining to gender, ethnicity and age. The data for use in machine learning training and evaluation is anonymized, and will not contain any personal information related to the patient. In addition we will also be careful and responsible about the needed complexity of the models, since this is directly connected to energy consumption and will have influence on the environment. Augeres strategy is to develop models with a complexity that are appropriate for the task, thus optimize energy cost vs. benefit from analysis.

14. Gender issues (Recruitment of women, gender balance and gender perspectives)

Augere's team is currently imbalanced as to gender, with 1 out of 5 full-time positions held by a woman. The company, however, has a policy to remedy this in future hirings, and will seek to achieve gender balance, and also encourage a mix of ethnicities and nationalities to ensure a wide range of viewpoints are available for decision making. The project leader for this project is a woman, who is also the Chief Medical Officer of Augere.

We are not aware of any gender or ethnicity related issues with polyp detection in the large bowel, but in line with sound AI development, we have a strong focus on maintaining diversity and avoiding bias in data collection, annotation and machine training.

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Curriculum vitae – Pål Halvorsen

*** ROLE IN THE PROJECT**

Project manager ☐ Work package leader ☐
Project partner ☒ Other (specify) ☐ …….

*** PERSONAL INFORMATION**

*Family name, First name:	Halvorsen, Pål		
*Date of birth:	26.12.1971	*Sex:	Male
*Nationality:	Norwegian		

*** HIGHER EDUCATION/OTHER TRAINING**

	Subjects/degree/	Name of institution, country
2001	*Dr. Scient (PhD)*	*Department of Informatics, University of Oslo, NO (6 months ahead of schedule)*
1997	*Cand.Scient (MSc)*	*Department of Informatics, University of Oslo, NO*

*** POSITIONS** (academic, business, industry, public sector, national or international organisations)

Current Position(s)

	Job title/name of employer/country
2018-	*Head of Department / Chief Research Scientist, SimulaMet - Simula Metropolitan Center for Digital Engineering, NO*
2019-	*Professor, Department of Informatics, OsloMet – Oslo Metropolitan University, NO*
2019-	*Professor II, Department of Informatics, University of Oslo, NO*
2016-	*CEO Forzasys AS, NO*

Previous positions held (list)

	Job title/name of employer/country
2005-18	*Chief Research Scientist, Simula Research Laboratory, NO*
2009-18	*Professor, Department of Informatics, University of Oslo, NO*
2002-09	*Associate Professor, Department of Informatics, University of Oslo, NO*

PROJECT MANAGEMENT EXPERIENCE (since 2014)

	Project/topic/role in project/funding from
2021-24	*AVATAR* (RESEARCHER, RCN Fripro, Interview training of child-welfare and law-enforcement professionals interviewing maltreated children supported via artificial avatars)
2020-22	*FFC* (RESEARCHER, Tromsø Research Foundation, Future Female Football Center)
2018-20	*AutoCap* (PROJECT LEADER, RCN BIA, Automatic Anomaly Detection in Video Capsule Endoscopy)
2019-20	*GIRD* (RESEARCHR, RCN FORNY, Gastro-Intestinal Real-time Detection)
2016	*DigSys* (PROJECT LEADER, RCN pre-project, Non-Invasive, Scalable Automatic Screening of the GI System)
2015-16	*VUE* (PROJECT LEADER, RCN FORNY, Video system for User Engagement based on in-video metadata, sport case study)
2014-17	*EONS* (PROJECT LEADER, RCN FRINATEK, Efficient Execution of Large Workloads on Elastic Resources)
2007-14	*iAd* (PROJECT LEADER@UiO, RCN SFI, Information Access Disruptions)
2017-20	*PRIVATON* (RESEARCHER, RCN, Protecting Shared Data with Privacy Automatons)
2018	*GastroEye* (RESEARCHER, Italian, GI video capsule analysis)
2016-19	*TACS* (RESEARCHER, RCN, Trans-Atlantic Corpore Sano)
2015-	*Corpore Sano* (RESEARCHER, own financing, virtual research centre, distributed systems)
2014-17	*Unified PCIe IO* (RESEARCHER, RCN BIA, Unified PCI Express for Distributed Component Virtualization)
2012-15	*TimeIn* (RESEARCHER, RCN, Traffic behaviour of interactive time-dependent thin streams on the modern Internet)
2012-15	*RITE* (RESEARCHER, EU, Reducing Internet Transport Latency)

EXPERIENCE FROM RELEVANT RESEARCH & INNOVATION ACTIVITIES (since 2014)

	Project/type of R&I activity and R&I content /role and tasks/funding from
2019-20	*GIRD* (RESEARCHR, RCN **FORNY**, Gastro-Intestinal Real-time Detection)

2014-17	*Unified PCIe IO* (RESEARCHER, RCN **BIA**, Unified PCI Express for Distributed Component Virtualization)
2015-16	*VUE* (PROJECT LEADER, RCN **FORNY**, Video system for User Engagement based on in-video metadata)
2018-20	*AutoCap* (PROJECT LEADER, RCN **BIA**, Automatic Anomaly Detection in Video Capsule Endoscopy)
2007-14	*iAd* (PROJECT LEADER@UiO, RCN **SFI**, Information Access Disruptions)

EXPERIENCE FROM NATIONAL/INTERNATIONAL COLLABORATION/NETWORKING (since 2014)

	Activity or project / tasks and responsibilities / context/programme/framework of the collaboration and names of key partners (companies, institutions)
2014 -	More than 50 TPC memberships, co-chair memberships, associate editorships for journals, etc. See full list: http://home.simula.no/~paalh/conferences.html

OTHER MERITS RELEVANT TO THE PROJECT

My research interests include multimedia and distributed systems, in particular, system performance, video analysis and delivery, sport and medical applications, machine/deep learning.

Total number of publications (journals, peer-review conferences): ~300
Full list at: http://home.simula.no/~paalh/publications/
According to Google Scholar (https://scholar.google.no/citations?user=hru0ei0AAAAJ&hl=en), I have about 4500 citations and an h-index of 33

10 selected publications (since 2019):

1. "A comprehensive analysis of classification methods in gastrointestinal endoscopy imaging", Debesh Jha, Sharib Ali, Steven Hicks, Vajira Thambawita, Hanna Borgli, Pia H. Smedsrud, Thomas de Lange, Konstantin Pogorelov, Xiaowei Wang, Philipp Harzig, Minh-Triet Tran, Wenhua Meng, Trung-Hieu Hoang, Danielle Dias, Tobey H. Ko, Taruna Agrawal, Olga Ostroukhova, Zeshan Khan, Muhammad Atif Tahir, Yang Liu, Yuan Chang, Mathias Kirkerød, Dag Johansen, Mathias Lux, Håvard D. Johansen, Michael A. Riegler, Pål Halvorsen, in Medical Image Analysis, Volume 70, May 2021
2. "Kvasir-Capsule, a video capsule endoscopy dataset", Pia H. Smedsrud, Vajira Thambawita, Steven A. Hicks, Henrik Gjestang,Oda Olsen Nedrejord, Espen Næss, Hanna Borgli, Debesh Jha, Tor Jan DerekBerstad, Sigrun L. Eskeland, Mathias Lux, Håvard Espeland, Andreas Petlund, Duc Tien Dang Nguyen, Enrique Garcia-Ceja, Dag Johansen, Peter T. Schmidt, Ervin Toth, Hugo L. Hammer, Thomas de Lange, Michael A. Riegler, and Pål Halvorsen, to appear in in Nature Scientific Data, 2021
3. "Real-Time Polyp Detection, Localisation and Segmentation in Colonoscopy Using Deep Learning", Debesh Jha, Sharib Ali, Nikhil Kumar Tomar, Håvard D. Johansen, Dag Johansen, Jens Rittscher, Michael A. Riegler, Pål Halvorsen, in IEEE Access, Volume 9, March 2021, pp. 40496 - 40510

4. "The EndoTect 2020 Challenge: Evaluation and Comparison of Classification, Segmentation and Inference Time for Endoscopy", Steven A. Hicks, Debesh Jha, Vajira Thambawita, Pål Halvorsen,Hugo L. Hammer, Michael A. Riegler, in Proceedings of International Conference on Pattern Recognition (ICPR), January 2021
5. "A Comprehensive Study on Colorectal Polyp Segmentation with ResUNet++, Conditional Random Field and Test-Time Augmentation", Debesh Jha, Pia H. Smedsrud, Dag Johansen, Thomas de Lange, Håvard D. Johansen, Pål Halvorsen, Michael A. Riegler, in IEEE Journal of Biomedical and Health Informatics, 2021
6. "Comparative validation of multi-instance instrument segmentation in endoscopy: results of the ROBUST-MIS 2019 challenge", Tobias Ross, Annika Reinke, Peter M. Full, Martin Wagner, Hannes Kenngott, Martin Apitz, Hellena Hempe, Diana Mindroc Filimon, Patrick Scholz, Thuy Nuong Tran, Pierangela Bruno, Pablo Arbeláez, Gui-Bin Bian, Sebastian Bodenstedt, Jon Lindström Bolmgren, Laura Bravo-Sánchez, Hua-Bin Chen, Cristina González, Dong Guo, Pål Halvorsen, Pheng-Ann Heng, Enes Hosgor, Zeng-Guang Hou, Fabian Isensee, Debesh Jha, Tingting Jiang, Yueming Jin, Kadir Kirtac, Sabrina Kletz, Stefan Leger, Zhixuan Li, Klaus H. Maier-Hein, Zhen-Liang Ni, Michael A. Riegler, Klaus Schoeffmann, Ruohua Shi, Stefanie Speidel, Michael Stenzel, Isabell Twick, Gutai Wang, Jiacheng Wang, Liansheng Wang, Lu Wang, Yujie Zhang, Yan-Jie Zhou, Lei Zhu, Manuel Wiesenfarth, Annette Kopp-Schneider, Beat P. Müller-Stich, Lena Maier-Hein, in Medical Image Analysis, November 2020
7. "HyperKvasir, a comprehensive multi-class imageand video dataset for gastrointestinal endoscopy", Hanna Borgli, Vajira Thambawita, Pia H. Smedsrud, Steven Hicks, Debesh Jha, Sigrun L. Eskeland, Kristin Ranheim Randel, Konstantin Pogorelov, Mathias Lux, Duc Tien Dang Nguyen, Dag Johansen, Carsten Griwodz, Hakon K.Stensland, Enrique Garcia-Cej, Peter T. Schmidt, Hugo L. Hammer, Michael A. Riegler, Pål Halvorsen, Thomas de Lange, in Nature Scientific Data, Vol. 7, 2020
8. "Medical Multimedia Systems and Applications", Pål Halvorsen, Michael Riegler, Klaus Schoeffmann, in Proceedings of ACM international conference on Multimedia (ACM MM), Nice, France, October 2019
9. "Bleeding detection in wireless capsule endoscopy videos - Color versus texture features", Konstantin Pogorelov, Shipra Suman, Fawnizu Azmadi Hussin, Aamir Saeed Malik, Olga Ostroukhova, Michael Riegler, Pål Halvorsen, Shiaw Hooi Ho, Khean-Lee Goh, in Journal of applied clinical medical physics, Vol. 20, No. 8, June 2019, pp. 141-154
10. "Deep Learning for Automatic Geneation of Endoscopy Reports", Steven Hicks, Pia H. Smedsrud, Michael A. Riegler, Thomas de Lange, Andreas Petlund, Sigrun L. Eskeland, Konstantin Pogorelov, Peter T. Schmidt, Pål Halvorsen, in Gastrointestinal Endoscopy, Volume 89, Issue 6, Supplement, June 2019

Granted Patents:

"Data segmentation, request and transfer method", Dominik Kaspar, Kristian R. Evensen, Paal E. Engelstad, Audun F. Hansen, Carsten Griwodz, Pål Halvorsen, US 20110213827

Curriculum vitae

*** ROLE IN THE PROJECT**

Project manager	☐	Work package leader	☒
Project partner	☐	Other (specify)	☐

……

*** PERSONAL INFORMATION**

*Family name, First name:	Espeland, Håvard Nygaard		
*Date of birth:	10.06.1983	*Sex:	Male
*Nationality:	Norwegian		

*** HIGHER EDUCATION/OTHER TRAINING**

	Subjects/degree/	Name of institution, country
2014	PhD	Dep. of Informatics, University of Oslo, Norway
2008	Master i informatikk	Dep. of Informatics, University of Oslo, Norway

*** POSITIONS** (academic, business, industry, public sector, national or international organisations)

Current Position

	Job title/name of employer/country
2019-	CTO, Augere Medical AS, Norway
2017-	Affiliated Researcher, Simula Research Laboratory, Norway

Previous positions held (list)

	Job title/name of employer/country
2017-2018	CTO, Forzasys AS, Norway
2014-2016	Adjunct Research Scientist, Simula Research Laboratory, Norway
2014	Post Doctor, Simula Research Laboratory, Norway
2013	Lecturer, NITH, Norway
2008-2014	Doctoral Research Fellow, Dep. Of Informatics, University of Oslo, Norway
2008-2014	Doctoral Research Fellow, Simula Research Laboratory, Norway

PROJECT MANAGEMENT EXPERIENCE (if applicable)

	Project/topic/role in project/funding from
2015-2016	POPART, Film Production Technology, Project Coordinator, EU H2020 Project
2015-2016	FLEXCAM, Film Production Technology, Project Manager, NFR Forny 2020 Project

EXPERIENCE FROM RELEVANT RESEARCH & INNOVATION ACTIVITIES (if applicable)

	Project/type of R&I activity and R&I content /role and tasks/funding from
2019-2020	GIRD, Gastro intestinal real-time polyp detection, Researcher, NFR FORNY 2020
2018-2020	Autocap, Automatic anomaly detection in video capsule endoscopy, Researcher, NFR BIA

OTHER MERITS RELEVANT TO THE PROJECT

- Publications, technical reports, peer-review assignments, etc.
- Presentations at workshops or conferences (national/international level)
- Positions in professional associations / networks

19 peer reviewed publications in journals / refereed proceedings.

2 patent applications.

Publications since 2018:

1. "Kvasir-Capsule, a video capsule endoscopy dataset", Pia H. Smedsrud, Vajira Thambawita, Steven A. Hicks, Henrik Gjestang,Oda Olsen Nedrejord, Espen Næss, Hanna Borgli, Debesh Jha, Tor Jan DerekBerstad, Sigrun L. Eskeland, Mathias Lux, Håvard Espeland, Andreas Petlund, Duc Tien Dang Nguyen, Enrique Garcia-Ceja, Dag Johansen, Peter T. Schmidt, Ervin Toth, Hugo L. Hammer, Thomas de Lange, Michael A. Riegler, and Pål Halvorsen, to appear in in Nature Scientific Data, 2021
2. “Efficient Live and On-Demand Tiled HEVC 360 VR Video Streaming”, M. Jeppsson, H. Espeland, T. Kupka, R. Langseth, A. Petlund, P. Qiaoqiao, C. Xue, D. Johansen, K. Pogorelov, H. K. Stensland et al., International Journal of Semantic Computing 13, no. 3 (2019): 367-391.
3. “Tradeoffs using Binary and Multiclass Neural Network Classification for Medical Multidisease Detection”, T. J. D. Berstad, M. Riegler, H. Espeland, T. de Lange, P. H. Smedsrud, K. Pogorelov, H. K. Stensland and P. Halvorsen, In 2018 IEEE International Symposium on Multimedia (ISM). IEEE, 2018.
4. “Efficient Live and on-Demand Tiled HEVC 360 VR Video Streaming”, M. Jeppsson, H. Espeland, T. Kupka, R. Langseth, A. Petlund, P. Qiaoqiao, C. Xue, K. Pogorelov, M. Riegler, D. Johansen et al., In 2018 IEEE International Symposium on Multimedia (ISM). Taichung, Taiwan: IEEE, 2018.

5. “Deep Learning and Handcrafted Feature Based Approaches for Automatic Detection of Angiectasia”, K. Pogorelov, O. Ostroukhova, A. Petlund, P. Halvorsen, T. de Lange, H. Espeland, T. Kupka, C. Griwodz and M. Riegler, In 2018 IEEE Conference on Biomedical and Health Informatics (BHI). IEEE, 2018.
6. “Deep Learning and Hand-crafted Feature Based Approaches for Polyp Detection in Medical Videos”, K. Pogorelov, O. Ostroukhova, M. Jeppsson, H. Espeland, C. Griwodz, T. de Lange, D. Johansen, M. Riegler and P. Halvorsen, In 31st IEEE CBMS International Symposium on Computer-Based Medical Systems. Karlstad, Sweden: IEEE, 2018.

Patents:

1. “Method for real-time detection of objects, structures or pattern in a video”, Espeland H, Riegler M, Augere Medical AS, Patent Application PCT/NO2020/050170, 2020
2. “VR VIDEO PLAYBACK METHOD, TERMINAL, AND SERVER”, Espeland H, et. al, Huawei Technologies Co. Ltd and Forzasys AS, Patent Application PCT/CN2019/087601, 2019

Full list of publications is available on personal website:

https://www.simula.no/people/haavares

Curriculum vitae

PLEASE NOTE: All items marked with * must be completed.

The maximum page limit is 4 pages. (It is not possible to upload an attachment that exceeds 4 pages). The page format must be A4 with 2 cm margins, single spacing and Arial, Calibri or Times New Roman 11-point font. *You should delete this box, and all non-applicable sections/boxes, when filling in the CV.*

* ROLE IN THE PROJECT

Project manager	☐	Work package leader	☐	
Project partner	☒	Other (specify)	☒	Principal Investigator

* PERSONAL INFORMATION

*Family name, First name:	Riegler, Michael Alexander		
*Date of birth:	18.09.1984	*Sex:	Male
*Nationality:	Austrian		

* HIGHER EDUCATION/OTHER TRAINING

	Subjects/degree/	Name of institution, country
2017	*Dr. Scient (PhD)*	*Department of Informatics, University of Oslo, NO (submitted 12 months ahead of schedule)*
2014	*Magister (Mag.)*	*Department of Informatics and Department of Economics, University of Klagenfurt, AT*

* POSITIONS (academic, business, industry, public sector, national or international organisations)

Current Position

	Job title/name of employer/country
2019-	*Chief Research Scientist, SimulaMet - Simula Metropolitan Center for Digital Engineering, NO*

Previous positions held (list)

	Job title/name of employer/country
2019-2020	*Adjunct Associate Professor, Kristiania University College, NO*
2018-2019	*Senior Research Scientist, SimulaMet- Simula Metropolitan Center for Digital Engineering, NO*

2017-2018	*Research Scientist, Simula Research Laboratory, NO*
2014-2017	*PhD Student, Simula Research Laboratory, NO*
2014	*Research Staff Member, Department of, University of Klagenfurt, AT*

PROJECT MANAGEMENT EXPERIENCE (if applicable)

	Project/topic/role in project/funding from
2021-2026	*Interview training of child-welfare and law-enforcement professionals interviewing maltreated children supported via artificial avatars (*Researcher, CRN Fripro, 12MNOK)
2020-2022	*FFC* (Researcher, Tromsø Research Foundation, Future Female Football Center)
2019-2024	*ReproAI* (Researcher, CRN FRIMEDBIO, improved assisted human reproduction technology using AI, 12MNOK)
2016	*DigSys* (Researcher, CRN pre-project, Non-Invasive, Scalable Automatic Screening of the GI System, 500KNOK)
2014-2017	*EONS* (Researcher, CRN FRINATEK, Efficient Execution of Large Workloads on Elastic Resources, 12MNOK)
2017-2020	*PRIVATON* (Researcher, CRN, Protecting Shared Data with Privacy Automatons, 12MNOK)
2018-2023	*PACER* (Researcher, CRN, Patient-Centric Engineering in Rehabilitation, 12MNOK)

EXPERIENCE FROM RELEVANT RESEARCH & INNOVATION ACTIVITIES (if applicable)

	Project/type of R&I activity and R&I content /role and tasks/funding from
2019-2020	*GIRD* (RESEARCHR, RCN **FORNY**, Gastro-Intestinal Real-time Detection)
2018-2020	*AutoCap* (Researcher, CRN BIA, Automatic Anomaly Detection in Video Capsule Endoscopy, 12MNOK)
2018	*GastroEye* (Researcher, Italian, GI video capsule analysis, 700KNOK)
2017-2019	*INTROMAT* (Researcher, CRN Lighthouse, INTROducing Mental health through Adaptive Technology, 72MNOK)

EXPERIENCE FROM NATIONAL/INTERNATIONAL COLLABORATION/NETWORKING (if applicable)

	Activity or project / tasks and responsibilities / context/programme/framework of the collaboration and names of key partners (companies, institutions)
2014-	Multimedial Workshop organization, Different roles, University of Delft, Netherlands

OTHER MERITS RELEVANT TO THE PROJECT

My research interests include machine learning, multimedia and distributed systems. In particular, my experience cover machine learning with a focus on deep learning and system performance.

Total number of publications (journals, peer-review conferences): ~219
Google Scholar https://scholar.google.no/citations?user=Vd_ApDoAAAAJ&hl=en
Number of citations: 2298, h-index: 26, i10-index: 60

10 selected publications (since 2019):

1. "A comprehensive analysis of classification methods in gastrointestinal endoscopy imaging", Debesh Jha, Sharib Ali, Steven Hicks, Vajira Thambawita, Hanna Borgli, Pia H. Smedsrud, Thomas de Lange, Konstantin Pogorelov, Xiaowei Wang, Philipp Harzig, Minh-Triet Tran, Wenhua Meng, Trung-Hieu Hoang, Danielle Dias, Tobey H. Ko, Taruna Agrawal, Olga Ostroukhova, Zeshan Khan, Muhammad Atif Tahir, Yang Liu, Yuan Chang, Mathias Kirkerød, Dag Johansen, Mathias Lux, Håvard D. Johansen, Michael A. Riegler, Pål Halvorsen, in Medical Image Analysis, Volume 70, May 2021
2. "Kvasir-Capsule, a video capsule endoscopy dataset", Pia H. Smedsrud, Vajira Thambawita, Steven A. Hicks, Henrik Gjestang,Oda Olsen Nedrejord, Espen Næss, Hanna Borgli, Debesh Jha, Tor Jan DerekBerstad, Sigrun L. Eskeland, Mathias Lux, Håvard Espeland, Andreas Petlund, Duc Tien Dang Nguyen, Enrique Garcia-Ceja, Dag Johansen, Peter T. Schmidt, Ervin Toth, Hugo L. Hammer, Thomas de Lange, Michael A. Riegler, and Pål Halvorsen, to appear in in Nature Scientific Data, 2021
3. "Real-Time Polyp Detection, Localisation and Segmentation in Colonoscopy Using Deep Learning", Debesh Jha, Sharib Ali, Nikhil Kumar Tomar, Håvard D. Johansen, Dag Johansen, Jens Rittscher, Michael A. Riegler, Pål Halvorsen, in IEEE Access, Volume 9, March 2021, pp. 40496 - 40510
4. "The EndoTect 2020 Challenge: Evaluation and Comparison of Classification, Segmentation and Inference Time for Endoscopy", Steven A. Hicks, Debesh Jha, Vajira Thambawita, Pål Halvorsen,Hugo L. Hammer, Michael A. Riegler, in Proceedings of International Conference on Pattern Recognition (ICPR), January 2021
5. "A Comprehensive Study on Colorectal Polyp Segmentation with ResUNet++, Conditional Random Field and Test-Time Augmentation", Debesh Jha, Pia H. Smedsrud, Dag Johansen, Thomas de Lange, Håvard D. Johansen, Pål Halvorsen, Michael A. Riegler, in IEEE Journal of Biomedical and Health Informatics, 2021
6. "Comparative validation of multi-instance instrument segmentation in endoscopy: results of the ROBUST-MIS 2019 challenge", Tobias Ross, Annika Reinke, Peter M. Full, Martin Wagner, Hannes Kenngott, Martin Apitz, Hellena Hempe, Diana Mindroc Filimon, Patrick Scholz, Thuy Nuong Tran, Pierangela Bruno, Pablo Arbeláez, Gui-Bin Bian, Sebastian Bodenstedt, Jon Lindström Bolmgren, Laura Bravo-Sánchez, Hua-Bin Chen, Cristina González, Dong Guo, Pål Halvorsen, Pheng-Ann Heng, Enes Hosgor, Zeng-Guang Hou, Fabian Isensee, Debesh Jha, Tingting Jiang, Yueming Jin, Kadir Kirtac, Sabrina Kletz, Stefan Leger, Zhixuan Li, Klaus H. Maier-Hein, Zhen-Liang Ni, Michael A. Riegler, Klaus Schoeffmann, Ruohua Shi, Stefanie Speidel, Michael Stenzel, Isabell Twick, Gutai Wang, Jiacheng Wang, Liansheng Wang, Lu Wang, Yujie Zhang, Yan-Jie Zhou, Lei Zhu, Manuel Wiesenfarth, Annette Kopp-Schneider, Beat P. Müller-Stich, Lena Maier-Hein, in Medical Image Analysis, November 2020
7. "HyperKvasir, a comprehensive multi-class imageand video dataset for gastrointestinal endoscopy", Hanna Borgli, Vajira Thambawita, Pia H. Smedsrud, Steven Hicks, Debesh Jha, Sigrun L. Eskeland, Kristin Ranheim Randel, Konstantin Pogorelov, Mathias Lux, Duc Tien Dang Nguyen, Dag Johansen, Carsten Griwodz, Hakon K.Stensland, Enrique Garcia-Cej, Peter T. Schmidt, Hugo L.

Hammer, Michael A. Riegler, Pål Halvorsen, Thomas de Lange, in Nature Scientific Data, Vol. 7, 2020

8. "Medical Multimedia Systems and Applications", Pål Halvorsen, Michael Riegler, Klaus Schoeffmann, in Proceedings of ACM international conference on Multimedia (ACM MM), Nice, France, October 2019
9. "Bleeding detection in wireless capsule endoscopy videos - Color versus texture features", Konstantin Pogorelov, Shipra Suman, Fawnizu Azmadi Hussin, Aamir Saeed Malik, Olga Ostroukhova, Michael Riegler, Pål Halvorsen, Shiaw Hooi Ho, Khean-Lee Goh, in Journal of applied clinical medical physics, Vol. 20, No. 8, June 2019, pp. 141-154
10. "Deep Learning for Automatic Geneation of Endoscopy Reports", Steven Hicks, Pia H. Smedsrud, Michael A. Riegler, Thomas de Lange, Andreas Petlund, Sigrun L. Eskeland, Konstantin Pogorelov, Peter T. Schmidt, Pål Halvorsen, in Gastrointestinal Endoscopy, Volume 89, Issue 6, Supplement, June 2019

Selected awards:

- One of the five ESHRE 2019 most promising researchers (ESRHE Young Ambassador), European Society of Human Reproduction and Embryology
- *Researcher of the Year 2018 at Simula Research Laboratory, Simula Research Laboratory*
- *One of four Rising Stars/Leaders in the multimedia research community, ACM SIGMM 2018*
- IEEE ISM 2018 Best paper award
- MediaEval 2018 Distinctive Mention award
- IEEE CBMS 2018 Best paper award
- *TEWI Hall of fame – 2017 Award from University of Klagenfurt for most successful alumni*
- *Award for best performing student 2012/2013 from the Faculty of Management and Economics at the University of Klagenfurt*

Member of:

- Expert group member on artificial intelligence in health, The Norwegian Board of Technology
- Member of the Academy of of Norway, Akademiet for yngre forskere

Curriculum vitae

* ROLE IN THE PROJECT

Project manager ☒ Work package leader ☐
Project partner ☐ Other (specify) ☐
……

* PERSONAL INFORMATION

*Family name, First name:	Smedsrud, Pia Helén		
*Date of birth:	23.11.1985	*Sex:	Female
*Nationality:	Norwegian		

* HIGHER EDUCATION/OTHER TRAINING

	Subjects/degree/	Name of institution, country
2016	MD	Department of Medicine, University of Oslo, Norway

*** POSITIONS** (academic, business, industry, public sector, national or international organisations)

Current Position

	Job title/name of employer/country
2019-	Chief Medical Officer, Augere Medical AS, Norway
2019-	PhD candidate, Augere Medical AS, Norway

Previous positions held (list)

	Job title/name of employer/country
2018-2019	Research trainee, Simula Research Laboratory, Norwaay
2017-2018	Resident, Department of Internal Medicine, Oslo University Hospital, Norway
2016-2018	Medical intern, Oslo University Hospital and City of Oslo, Norway

2014-2015	Medical student with license, Department of Orthopedic surgery, Oslo University Hospital, Norway

EXPERIENCE FROM RELEVANT RESEARCH & INNOVATION ACTIVITIES (if applicable)

	Project/type of R&I activity and R&I content /role and tasks/funding from
2018-2020	GIRD – Gastro-intestinal Real-time detection, Responsible for data collection and protocol, FORNY - RCN
2019-	BROCaD – Bridging the Disciplinary gap for Computer Aided Diagnosis in Colonoscopy; Detection, Evaluation and Diagnostics, PhD candidate, Nærings-PhD - RCN
2018-2019	AutoCap – Automatic anomaly detection in video capsule endoscopy, researcher, BIA - RCN

OTHER MERITS RELEVANT TO THE PROJECT

- Publications, technical reports, peer-review assignments, etc.
- Presentations at workshops or conferences (national/international level)
- Positions in professional associations / networks

Publications

Google Scholar https://scholar.google.com/citations?user=QzobgSUAAAAJ&hl=en
Number of citations: 130, h-index: 5, i10-index: 3

1. "A comprehensive analysis of classification methods in gastrointestinal endoscopy imaging", Debesh Jha, Sharib Ali, Steven Hicks, Vajira Thambawita, Hanna Borgli, Pia H. Smedsrud, Thomas de Lange, Konstantin Pogorelov, Xiaowei Wang, Philipp Harzig, Minh-Triet Tran, Wenhua Meng, Trung-Hieu Hoang, Danielle Dias, Tobey H. Ko, Taruna Agrawal, Olga Ostroukhova, Zeshan Khan, Muhammad Atif Tahir, Yang Liu, Yuan Chang, Mathias Kirkerød, Dag Johansen, Mathias Lux, Håvard D. Johansen, Michael A. Riegler, Pål Halvorsen, in Medical Image Analysis, Volume 70, May 2021
2. "Kvasir-Capsule, a video capsule endoscopy dataset", Pia H. Smedsrud, Vajira Thambawita, Steven A. Hicks, Henrik Gjestang,Oda Olsen Nedrejord, Espen Næss, Hanna Borgli, Debesh Jha, Tor Jan DerekBerstad, Sigrun L. Eskeland, Mathias Lux, Håvard Espeland, Andreas Petlund, Duc Tien Dang Nguyen, Enrique Garcia-Ceja, Dag Johansen, Peter T. Schmidt, Ervin Toth, Hugo L. Hammer, Thomas de Lange, Michael A. Riegler, and Pål Halvorsen, to appear in in Nature Scientific Data, 2021
3. "A Comprehensive Study on Colorectal Polyp Segmentation with ResUNet++, Conditional Random Field and Test-Time Augmentation", Debesh Jha, Pia H. Smedsrud, Dag Johansen, Thomas de Lange, Håvard D. Johansen, Pål Halvorsen, Michael A. Riegler, in IEEE Journal of Biomedical and Health Informatics, 2021
4. "HyperKvasir, a comprehensive multi-class imageand video dataset for gastrointestinal endoscopy", Hanna Borgli, Vajira Thambawita, Pia H. Smedsrud, Steven Hicks, Debesh Jha, Sigrun L. Eskeland, Kristin Ranheim Randel, Konstantin Pogorelov, Mathias Lux, Duc Tien Dang Nguyen, Dag Johansen, Carsten Griwodz, Hakon K.Stensland, Enrique Garcia-Cej, Peter T. Schmidt, Hugo L.

Hammer, Michael A. Riegler, Pål Halvorsen, Thomas de Lange, in Nature Scientific Data, Vol. 7, 2020

5. "Kvasir-seg: a segmented polyp dataset", Debesh Jha, Pia H Smedsrud, Michael A Riegler, Pål Halvorsen, Thomas de Lange, Dag Johansen, Håvard D Johansen, in International Conference on Multimedia Modeling, January 2020
6. "Resunet++: An advanced architecture for medical image segmentation", Debesh Jha, Pia H Smedsrud, Michael A Riegler, Dag Johansen, Thomas De Lange, Pål Halvorsen, Håvard D Johansen, in 2019 IEEE International Symposium on Multimedia (ISM), December 2019
7. "ACM Multimedia BioMedia 2019 Grand Challenge Overview", Steven Hicks, Michael Riegler, Pia Smedsrud, Trine B Haugen, Kristin Ranheim Randel, Konstantin Pogorelov, Håkon Kvale Stensland, Duc-Tien Dang-Nguyen, Mathias Lux, Andreas Petlund, Thomas de Lange, Peter Thelin Schmidt, Pål Halvorsen, Proceedings of the 27th ACM International Conference on Multimedia, 2019
8. "Deep Learning for Automatic Generation of Endoscopy Reports", Steven Hicks, Pia H. Smedsrud, Michael A. Riegler, Thomas de Lange, Andreas Petlund, Sigrun L. Eskeland, Konstantin Pogorelov, Peter T. Schmidt, Pål Halvorsen, in Gastrointestinal Endoscopy, Volume 89, Issue 6, Supplement, June 2019
9. "Tradeoffs using binary and multiclass neural network classification for medical multidisease detection", Tor Jan Derek Berstad, Michael Riegler, Håvard Espeland, Thomas de Lange, Pia Helen Smedsrud, Konstantin Pogorelov, Håkon Kvale Stensland, Pål Halvorsen, in 2018 IEEE International Symposium on Multimedia (ISM), 2018
10. "Deep learning based disease detection using domain specific transfer learning", Steven A Hicks, Pia H Smedsrud, Pål Halvorsen, Michael Riegler, MediaEval, 2018

Presentations

1. Kunstig intelligens for endoskopi - Automatisk deteksjon av lesjoner i sanntid - Norsk Gastroenterologisk Forening annual meeting 2019
2. Maskinlæring for automatisk deteksjon av angiektasi i tynntarm - Norsk Gastroenterologisk Forening annual meeting 2020
3. Augere Medical - Reducing Human Variability in Medicine, presentation in DNB Healthcare Prize Finals 2019

Curriculum vitae

* ROLE IN THE PROJECT

Project manager	☐	Work package leader	☐
Project partner	☒	Other (specify)	☐ .....

* PERSONAL INFORMATION

*Family name, First name:	de Lange, Thomas		
*Date of birth:	17.09.1960	*Sex:	Male
*Nationality:	Swedish		

* HIGHER EDUCATION/OTHER TRAINING

	Subjects/degree/	Name of institution, country
2006	PhD	University of Oslo, Norway
1999	Specialist in Gastroenterology	Ullevål University Hospital, Norway
1997	Specialist in Internal Medicine	Northern Älvsborgs County Hospital
1989	MD	Université Louis Pasteur, Strasbourg, France

* **POSITIONS** (academic, business, industry, public sector, national or international organisations)

Current Position

	Job title/name of employer/country
2019-	Chief Medical Scientist, Augere Medical AS, Norway (20% position)
2019-	Senior consultant and associate professor, Sahlgrenska University Hospital and University of Gothenburg, Sweden

Previous positions held (list)

	Job title/name of employer/country
2019-2020	Senior Scientist, Department om Medical Research, Bærum Hospital, Vestre Viken Hospital Trust, (20% position)
2017-2019	Head, Centre for Post-Graduate Education South East Norway, Oslo University Hospital, Norway
2017-2019	Associate professor II, Institute of Clinical Medicine, University of Oslo, Norway

2014-2017	Head of Bowel Cancer Screening in Norway, Cancer Registry of Norway
2014-2017	Head of Regional Gastrointestinal Endoscopy Training System, Oslo University Hospital, South-Eastern Norway Regional Health Authority
2006-2014	Senior Consultant and head of Gastroenterology, Bærum Hospital, Vestre Viken Hospital Trust, Norway
2001-2006	PhD student and Lecturer, Faculty of Medicine, University of Oslo, Norway

PROJECT MANAGEMENT EXPERIENCE (if applicable)

	Project/topic/role in project/funding from
2011-2017	Bowel Cancer Screening in Norway – a randomized control trial for colorectal cancer screening inviting 140.000 persons, principal investigator, funding from Ministry of health
2014-	Development of artificial Intelligence to improve the quality of gastrointestinal endoscopy. An interdisciplinary project where computer and medical scientists collaborate to develop algorithms and systems for automatic lesion detection and interpretation in gastrointestinal endoscopies.
2011-2017	Member of the steering committee of Gastronet, the National registry for quality improvement in gastrointestinal endoscopy
2011-	Leading positions in several institutions where main tasks were project management and development of the organization

OTHER MERITS RELEVANT TO THE PROJECT

Major Collaborations in medical technologies

Outside Norway
Sharib Ali, Senior Postdoctoral Researcher at University of Oxford (Computer vision and deep learning scientist), UK

Ervin Toth, Senior Consultant in gastroenterology and Associate Professor, Skåne University Hospital and University of Lund, Sweden

Peter Thelin Schmidt, Head of research, Ersta Hospital and associate professor, Karolinska institutet, Sweden

Within Norway
Pål Halvorsen, *Topic:* Medical technologies, Simula Research Laboratory, University of Oslo, Professor
Michael Riegler, *Assocoate professor,* Simula Metropolitan Center for Digital Engineering

Stephan Brackman, Senior consultant in Gastroenterology, Akershus University Hospital and associate professor, University of Oslo, Norway

Research projects since 2011

Interactive Dynamic Referral Interface (IDRI) (Interactive user interface for generating referrals to gastroenterologists). Role: Project leader

DigSys project (Non-Invasive, Scalable Automatic Screening of the Digestive System). Role: Medical leader

Bowel Cancer Screening in Norway (BCSN)- a Randomized Controlled Trial (RCT) inviting 140.000 person to compare two colorectal cancer screening methods, the project also includes several sub-studies regarding lifestyle and psychological reactions related to screening. Role: Project leader and principal investigator

Selected Publications 2016-2021

1. Hicks Steven, V Thambawita , H Gjestang , O Nedrejord , E Næss , H Borgli , D Jha , T Berstad , S Eskeland , M Lux , H Espeland , A Petlund , D Dang Nguyen , E Garcia-Ceja, D Johansen, P Schmidt , E Toth , H Hammer , **T de Lange**, M Riegler , P Halvorsen (2021) Kvasir-Capsule, a video capsule endoscopy dataset. Sci Data In press
2. Randel, Kristin, E. Botteri, **T. de Lange**, A Schult, S Eskeland, B El-Safadi, E Norvard, N Bolstad, M Bretthauer, G Hoff, Ø Holme, (2021) Immunochemical testing strategies for colorectal cancer screening in Europe. Endoscopy In Review
3. Schult Anna Lisa, E Botteri, G Hoff, Ø Holme, M Bretthauer, K Ranheim Randel, E Haagensen Gulichsen, B El-Safadi, I Barua, C Munck , L Nilsen, H Svendsen, **T de Lange** (2021) Opioids to prevent painful colonoscopies in women on-demand versus pre-examination administration: A randomized controlled trial Endoscopy In review
4. Schult Anna L, E Botteri, G Hoff, K R. Randel, E Dalén, S Eskeland, Ø Holme, **T de Lange, (2021)** The role of bowel symptoms in colorectal cancer screening participants: a cross-sectional study BMJ Open In review
5. Jha, D., P. H. Smedsrud, D. Johansen, **T. de Lange**, H. Johansen, P. Halvorsen and M. Riegler (2021). "A Comprehensive Study on Colorectal Polyp Segmentation with ResUNet++, Conditional Random Field and Test-Time Augmentation." IEEE J Biomed Health Inform **PP**: 1-1.
6. Randel, K. R., A. L. Schult, E. Botteri, G. Hoff, M. Bretthauer, G. Ursin, E. Natvig, P. Berstad, A. Jorgensen, P. K. Sandvei, M. E. Olsen, S. O. Frigstad, O. Darre-Naess, E. R. Norvard, N. Bolstad, H. Korner, A. Wibe, K. A. Wensaas, **T. de Lange** and O. Holme (2020). "Colorectal Cancer Screening With Repeated Fecal Immunochemical Test Versus Sigmoidoscopy: Baseline Results From a Randomized Trial." Gastroenterology.
7. Kværner, A. S., E. Birkeland, C. Bucher-Johannessen, E. Vinberg, J. I. Nordby, H. Kangas, V. Bemanian, P. Ellonen, E. Botteri, E. Natvig, T. Rognes, E. Hovig, R. Lyle, O. H. Ambur, W. M. De Vos, S. Bultman, A. Hjartåker, R. Landberg, M. Song, G. Ursin, K. R. Randel, **T. de Lange**, G. Hoff, Ø. Holme, P. Berstad and T. B. Rounge (2020). The CRCbiome study: a large prospective cohort study examining the role of lifestyle and the gut microbiome in colorectal cancer screening participants, Cold Spring Harbor Laboratory.
8. Borgli, H., V. Thambawita, P. H. Smedsrud, S. Hicks, D. Jha, S. L. Eskeland, K. R. Randel, K. Pogorelov, M. Lux, D. T. D. Nguyen, D. Johansen, C. Griwodz, H. K. Stensland, E. Garcia-Ceja, P. T. Schmidt, H. L. Hammer, M. A. Riegler, P. Halvorsen and **T. de Lange** (2020). "HyperKvasir, a comprehensive multi-class image and video dataset for gastrointestinal endoscopy." Sci Data **7**(1): 283.
9. Randel, K. R., E. Botteri, K. M. K. Romstad, S. O. Frigstad, M. Bretthauer, G. Hoff, **T. de Lange** and O. Holme (2019). "Effects of Oral Anticoagulants and Aspirin on Performance of Fecal Immunochemical Tests in Colorectal Cancer Screening." Gastroenterology **156**(6): 1642-1649 e1641.
10. Hoff, G., G. Ursin, M. Loberg, **T. de Lange**, E. Skovlund and O. Holme (2019). "Continuous development of colorectal cancer screening programs." Acta Oncol **58**(6): 822-823.
11. Hoff, G., **T. de Lange**, M. Bretthauer, S. Dahler, F. A. Halvorsen, G. Huppertz-Hauss, O. Hoie, O. Kjellevold, V. Mortiz, P. Sandvei, B. Seip and O. Holme (2019). "Registration bias in a clinical quality register." Endosc Int Open **7**(1): E90-E98.
12. Hicks, S., P. H. Smedsrud, M. A. Riegler, **T. de Lange**, A. Petlund, S. L. Eskeland, K. Pogorelov, P. T. Schmidt and P. Halvorsen (2019). DEEP LEARNING FOR AUTOMATIC GENERATION OF ENDOSCOPY REPORTS. Gastrointestinal Endoscopy.
13. Valori, R., G. Cortas, **T. de Lange**, O. S. Balfaqih, M. de Pater, P. Eisendrath, P. Falt, I. Koruk, A. Ono, N. Rustemovic, E. Schoon, A. Veitch, C. Senore, C. Bellisario, S. Minozzi, C. Bennett, M. Bretthauer, M. Dinis-Ribeiro, D. Domagk, C. Hassan, M. F. Kaminski, C. J. Rees, C. Spada, R. Bisschops and M. Rutter (2018). "Performance measures for endoscopy services: a European Society of Gastrointestinal Endoscopy (ESGE) Quality Improvement Initiative." Endoscopy **50**(12): 1186-1204.
14. Eskeland, S. L., C. S. Rueegg, C. Brunborg, L. Aabakken and **T. de Lange** (2018). "Electronic checklists improve referral letters in gastroenterology: a randomized vignette survey." Int J Qual Health Care **30**(6): 450-456.
15. Skyrud, K. D., T. A. Myklebust, F. Bray, M. T. Eriksen, **T. de Lange**, I. K. Larsen and B. Moller (2017). "How Many Deaths from Colorectal Cancer Can Be Prevented by 2030? A Scenario-Based Quantification of Risk Factor Modification, Screening, and Treatment in Norway." Cancer Epidemiol Biomarkers Prev **26**(9): 1420-1426.
16. **Lange T de**, K. R. Randel, A. L. Schult, M. D. Knudsen, B. Kirkoen, E. Botteri, P. Berstad, A. Jorgensen, G. Ursin, M. Bretthauer and G. Hoff (2017). "Sigmoidoscopy and faecal occult blood test - a comparative screening trial." Tidsskr Nor Laegeforen **137**(10): 727-730.
17. Riegler, M., K. Pogorelov, S. L. Eskeland, P. T. Schmidt, Z. Albisser, D. Johansen, C. Griwodz, P. Halvorsen and **T. de Lange** (2017). "From Annotation to Computer-Aided Diagnosis." ACM Transactions on Multimedia Computing, Communications, and Applications **13**(3): 1-26.
18. Eskeland, S. L., C. Brunborg, C. S. Rueegg, L. Aabakken and **T. de Lange** (2017). "Assessment of the effect of an Interactive Dynamic Referral Interface (IDRI) on the quality of referral letters from general practitioners to gastroenterologists: a randomised cross-over vignette trial." BMJ Open **7**(6): e014636.
19. Eskeland, S. L., C. Brunborg, B. Seip, K. Wiencke, O. Hovde, T. Owen, E. Skogestad, G. Huppertz-Hauss, F. A. Halvorsen, K. Garborg, L. Aabakken and **T. de Lange** (2016). "First quality score for referral letters in gastroenterology-a validation study." BMJ Open **6**(10): e012835.

Peered reviewed full text papers at computer science conferences

1. Jha, D., P. H. Smedsrud, M. A. Riegler, P. Halvorsen, **T. de Lange**, D. Johansen and H. D. Johansen (2020). Kvasir-seg: A segmented polyp dataset. International Conference on Multimedia Modeling, Springer, Cham.
2. Jha, D., S. A. Hicks, K. Emanuelsen, H. Johansen, D. Johansen, **T. de Lange**, M. A. Riegler and P. Halvorsen (2020). "Medico Multimedia Task at MediaEval 2020: Automatic Polyp Segmentation." arXiv preprint arXiv:2012.15244.
3. Jha, D., S. Ali, K. Emanuelsen, S. A. Hicks, E. Garcia-Ceja, M. A. Riegler, **T. de Lange**, P. T. Schmidt, H. D. Johansen and D. Johansen (2020). "Kvasir-Instrument: Diagnostic and therapeutic tool segmentation dataset in gastrointestinal endoscopy." International Conference on Multimedia Modeling
4. Pogorelov, K., M. Riegler, P. Halvorsen, **T. de Lange**, K. R. Randel, D.-T. Dang-Nguyen, M. Lux and O. Ostroukhova (2018). Medico Multimedia Task at MediaEval 2018. Working Notes Proceedings of the MediaEval 2018 Workshop.
5. Hicks, S. A., M. Riegler, K. Pogorelov, K. V. Ånonsen, **T. de Lange**, D. Johansen, M. Jeppsson, K. R. Randel, S. L. Eskeland and P. Halvorsen (2018). Dissecting Deep Neural Networksfor Better Medical Image Classification and Classification Understanding. 31st IEEE CBMS International Symposium on Computer-Based Medical Systems. Karlstad.

Presentations at workshops and conferences (national/international level)

November 2021, Danish Surgical Society Annual meeting, Copenhagen
May 2021, Swedish national congress in Gastroenterology, Lennart Wehlin Honorary Lecture, Artificial Intelligence to improve quality in endoscopy**, Honorary Lecture**
April 2021, Linköping University Hospital, Days of Endoscopy The potential of AI in endoscopy, Sweden
March 2021, AI Med Virtual conference from USA, Developing AI in GI endoscopy Essentials in data quality, invited speaker
January 2020 SADE course (advanced endoscopy), **2020 Copenhagen**, "AI in gastrointestinal endoscopy" invited speaker
The 1st Canadian Association of Gastroeneterology Quality Symposium, Training: the Key to Cost Effective Endoscopy, Toronto February 2018. "The Norwegian Endoscopy training system"

Positions in professional associations / networks

Member of the European Society of Gastrointestinal Endoscopy's Quality Improvement Committee 2015-

Member of the World Endoscopy Organisations' Documentation & Standardization Committee 2008-

Member of the SADE board 2012-2017

Member of the steering committee of the National Quality Assurance Registry for Endoscopy, Gastronet 2009-2017

Member of the Editorial Board World Journal of Gastrointestinal Endoscopy, California, USA, *2013-2017*
Member of the Editorial Board World Journal of Gastroenterology, California, USA, *2013-*
Member of the specialty committee of internal medicine 2006-2007

Attachment to grant application for an Innovation Project for the Industrial Sector.
Project title: Improved AI for Colonoscopy and Clinical Evaluation

Information about applicant and partner companies

Company name:	Augere Medical AS		
Enterprise no.:	921 501 684	Year established:	2018
Company website:	www.augere.md		

Key figures for most recent accounting year (all figures to be provided in NOK million). ***Specify year for the accounts (FTE= Full time equivalents):*** 2019 (latest completed accounts)			
No. of employees:	12	No. of FTEs performed by own employees:	6,4
No. of R&D personnel:	6	No. of R&D FTEs performed by own employees:	5,2
Annual turnover:			3,2 MNOK
Balance sheet total:			3,9 MNOK
Earnings:			-0,6 MNOK
Total R&D expenditures:			4,5 MNOK
Information about ownership:			
Do one or more enterprises hold an ownership interest of 25% or more in the company? (Yes/No)			No
Does the company hold an ownership interest of 25% or more in one or more enterprises? (Yes/No)			No
Is the company part of larger concern? (Yes/No) If so, provide the name of the concern:			No
Contact person for annual report/annual accounts and further information about the company:			
Name and email address of contact person:		Andreas Petlund, andreas@augere.md	

Augere Medical (AM) is a technology startup founded in 2018, spun out from Simula Research Laboratory. The company's first product is a decision support tool for improving detection of lesions during colonoscopies. The company's technology is based on more than ten years of research from Simula in the field of AI in medicine (internationally they are one of the leading players in the field of AI for GI endoscopy). The technology delivered by Augere has been validated, partially through an RCN "FORNY" project, which has laid the ground for an in-silico trial that documents the technology for regulatory approval in the EU. Augere has in April 2021 completed a financing round where 7 million NOK of private capital has been invested in the company to partially finance the first hospital clinical trials of the technology. The first product is expected to be approved and released on the European market within the next 2 years. The Augere team has a unique combination of skills within clinical research, real-time processing, computer vision, and machine learning (ML), essential to be the leading provider of next generation real-time decision support tools for health applications.

Attachment to grant application for an Innovation Project for the Industrial Sector.
Project title: Improved AI for Colonoscopy and Clinical Evaluation

Information about applicant and partner companies

Company name:	Simula Metropolitan Center for Digital Engineering AS		
Enterprise no.:	920 203 612	Year established:	2018
Company website:	www.simulamet.no		

Key figures for most recent accounting year (all figures to be provided in NOK million). ***Specify year for the accounts (FTE= Full time equivalents):***			
No. of employees:	59	No. of FTEs performed by own employees:	47,5
No. of R&D personnel:	59	No. of R&D FTEs performed by own employees:	47,5
Annual turnover:			72 170 kNOK
Balance sheet total:			45 536 kNOK
Earnings:			6 807 kNOK
Total R&D expenditures:			100 %
Information about ownership:			
Do one or more enterprises hold an ownership interest of 25% or more in the company? (Yes/No)			No
Does the company hold an ownership interest of 25% or more in one or more enterprises? (Yes/No)			No
Is the company part of larger concern? (Yes/No) If so, provide the name of the concern: Simula Research Laboratory AS			Yes
Contact person for annual report/annual accounts and further information about the company:			
Name and email address of contact person:		Monica Eriksen, monica@simula.no	

Simula Metropolitan Center for Digital Engineering (SimulaMet) is a new research unit that is jointly owned by Simula Research Laboratory and OsloMet – Oslo Metropolitan University. It is the home of Simula's research activities on networks and communications, machine learning and IT management, and it is OsloMet´s strategic partner in research and postgraduate education. SimulaMet is organized as a limited company.

Except for research itself, SimulaMet does not sell products, and thus, have not particular markets. The research center has its focus areas as listed above, but has no particular target application scenarios or customers. That said, the partner research department (Holistic Systems) has focus areas directly matching the proposal. The department has for a long time investigated AI-based systems in the areas of health, sports and environment studies – for real-world environments and users. Researchers from HOST have been working on novel AI analysis methods for medical procedures for approx 8 years. The research department has a good position in the research community, having papers being cited, asked to organize workshops and competitions, and requests for collaborations.

SimulaMet's goals and objectives in the proposed project are to produce interesting and relevant research and generate ideas potentially being used by industry or society in general. This project targets a real-world open challenge, and the potential for impact is large. Thus, we seek interesting challenges and research problems, that can result in good published papers, student theses, and research prototypes, i.e., the value for our research department is the research, the prototypes, experiences and the resulting papers that will strengthen our research profile and can be used further in our future research in AI, video analysis and sports in general. The proposal aims for procurement of time from SimulaMet researchers. We will involve our researchers in HOST already having the experience in the area of AI, sports and video analysis.