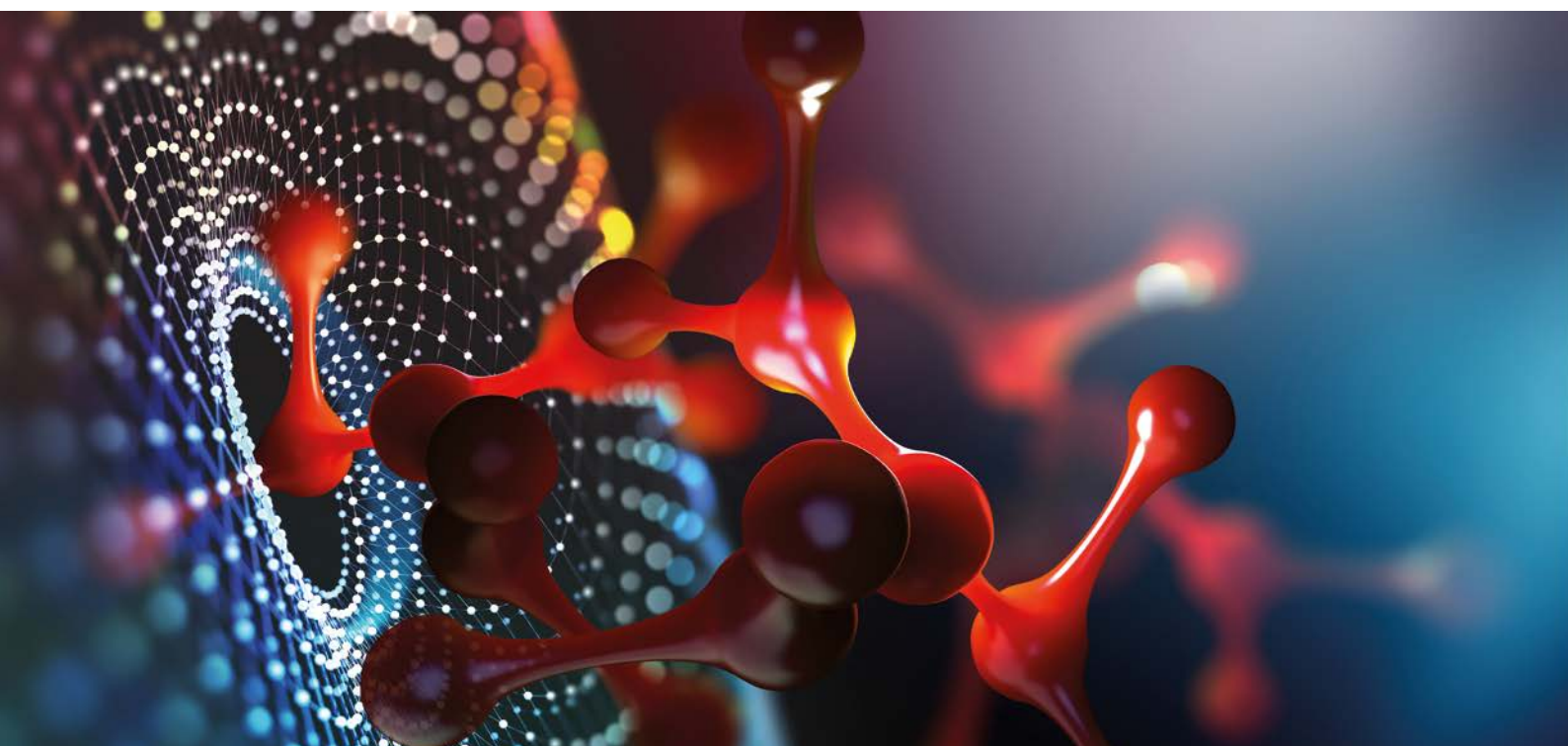




GENOLIER
INNOVATION
NETWORK

GENOLIER INNOVATION NETWORK

SCIENTIFIC REPORT 2020



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Foreword: Precision medicine and outcome research

In 2020, the entire world experienced the SARS-CoV-2 pandemic, and just like all healthcare workers, the scientific community as well had to handle mayhem created by COVID-19: temporary closure of institutions and laboratories, cancellations or postponements of scientific events and training programs.

Needless to say that as healthcare provider, Swiss Medical Network did not escape the rule, and Genolier Innovation Network tried, in the same way, to operate the best it could.

The 2019-edition of Genolier Innovation Network's Scientific Report covered the research programs conducted during its first year of activity. By pointing out new challenges threatening the population's health (pandemics, resistances to therapeutic agents etc.), this report called for innovative strategies leading to total healthcare and value-based medicine.

An objective, we continued to pursue in 2020, along with the application of the so-called "Systems Thinking/Systems Doing" policy, in which the interconnections between the pre-clinical and clinical domains were emphasized, thus linking the analysis of complex health problems to the identification of potential solutions.

The "red thread" of the conducted scientific programs leads to personalized medicine and outcome measures and research. Whilst personalized medicine covers the paradigm shift from "one-size-fits-all" treatments to a customized, state-of-the-art and tailor-made therapy for every single patient, the outcome measures and research are embedded in the "value-based medicine" concept (efficacy, cost reduction). This enters the framework of integrated and person-centered care, the path Swiss Medical Network is embarking on.

The present moment clearly proves that the vulnerability of our health ecosystem to extreme situations and emergencies does not belong to the past – it actually reminds us that we urgently need to build resilience through predictive research, personalized medicine and participative healthcare, and all this at reasonable costs.

Jacques Bernier, MD

Chief Science Officer

Genolier Innovation Network

In a nutshell...

STRATEGY

- Besides translational and clinical research, focus on PROM's and PREM's-research programs, leading to integrated, person centered health-care and value-based medicine;
- Accelerate Innovation and Development-Transfer to the clinic (especially in precision medicine);
- Promote scientific collaborations with regional, national and international bodies (e.g. Réseau Romand d'Oncologie, ETH Zurich, SAKK, EORTC, HSCI Harvard);
- Priority-alignment in accordance with current biomedical research-lines in other major institutions.

STRUCTURE AND ORGANIZATION - THE GENOLIER INNOVATION NETWORK PROJECT STEERING COMMITTEE

- Promotes innovations through participative and interactive processes;
- Develops "bench to bedside" ecosystems in order to guarantee access to clinical studies;
- Lays the foundation for concerted actions among researchers within Swiss Medical Network (also through consolidation of databases).

OPERATIONAL ASPECTS

- Genolier Innovation Network conducts prospective clinical trials in full compliance with quality assurance and bioethical requirements;
- It forecasts and monitors real-time requirements of research scientists;
- It promotes scientific education/training programs.





General considerations: The research gate to total Health

For Genolier Innovation Network, the fundamental pre-requisites for a successful development in healthcare research are:

- Definition of clear objectives and concentration of all available resources on specific research programs, in order to constantly improve the value of diagnostic and therapeutic procedures applied within Swiss Medical Network hospitals and competence centers;
- Multi-Disciplinarity: concerted actions are essential components in healthcare research, both, between scientists and clinicians, and between medical teams from different specialties and Swiss Medical Network sites;
- Focus on **value-based medicine** and **total health research-projects**; innovative solutions for improving population's overall health, optimising patients' treatment experience and reducing per-capita therapy-costs;
- Quality assurance procedures, guaranteeing that all research programs conducted at Swiss Medical Network are carried out in accordance with applicable national and international regulations and directives (Quality Assurance Systems, audits, GCP, GMP, etc.).

Research & Development is a venture of perpetual questioning. In healthcare, the continuous challenges clinicians face along the track to innovation, are part of those mandatory steps to enhance the existing knowledge and to translate it into new biomedical standards. It is Genolier Innovation Network's vocation to accompany the research scientists of Swiss Medical Network along this track and to provide them with all assistance needed to concretize their projects on the way to integrated care.



Genolier Innovation Hub

As cross-sectoral development platform of Swiss Medical Network, Genolier Innovation Hub brings research advances into clinical practice. Located at the heart of the Genolier Healthcare Campus, the Hub tightly liaises with Genolier Innovation Network.

Both platforms pursue the vision of fostering strategic interactions between scientists and physicians, accelerating the transfer of innovation from bench to bedside.

To achieve this goal, Genolier Innovation Hub will welcome research companies, whose programs have reached their late stage of experimental development, with pharmaceutical compounds or equipment ready to test in a clinical setting.

Thanks to its dynamic and collaborative environment, the Hub will provide strong support to the stakeholders for consolidating their Research and Development processes and optimizing knowledge transfer phases, within the framework of prospective clinical studies.

By bringing together, at its 10.000 m² site, individuals and companies from Med-tech, Pharma, Digital Technology & Bioscience fields, Genolier Innovation Hub will provide access to the technical and clinical platforms of Clinique de Genolier, the Genolier Healthcare Campus, as well as other clinical sites of Swiss Medical Network. Its state-of-the-art conference – and meeting facilities will open up the scope of educational and training models in an inspiring environment.

The mutual integration of Genolier Innovation Hub and Genolier Innovation Network is a key factor for the success of future R&D programs conducted within and beyond Swiss Medical Network.

Research Organization & Structure

While, in 2019, Genolier Innovation Network's first action consisted in establishing its Advisory Board and Scientific Committee, 2020 offered the opportunity to consolidate the scientific platform thanks to the creation of its Project Steering Committee.

The vocation of this latter is:

- To strengthen Swiss Medical Network's position as a biomedical research network;
- To facilitate innovations through participative and interactive processes, both inside Swiss Medical Network and in collaboration with other national and international research bodies;
- To promote research strategies aiming at a mutual integration of Genolier Innovation Hub and Genolier Innovation Network.

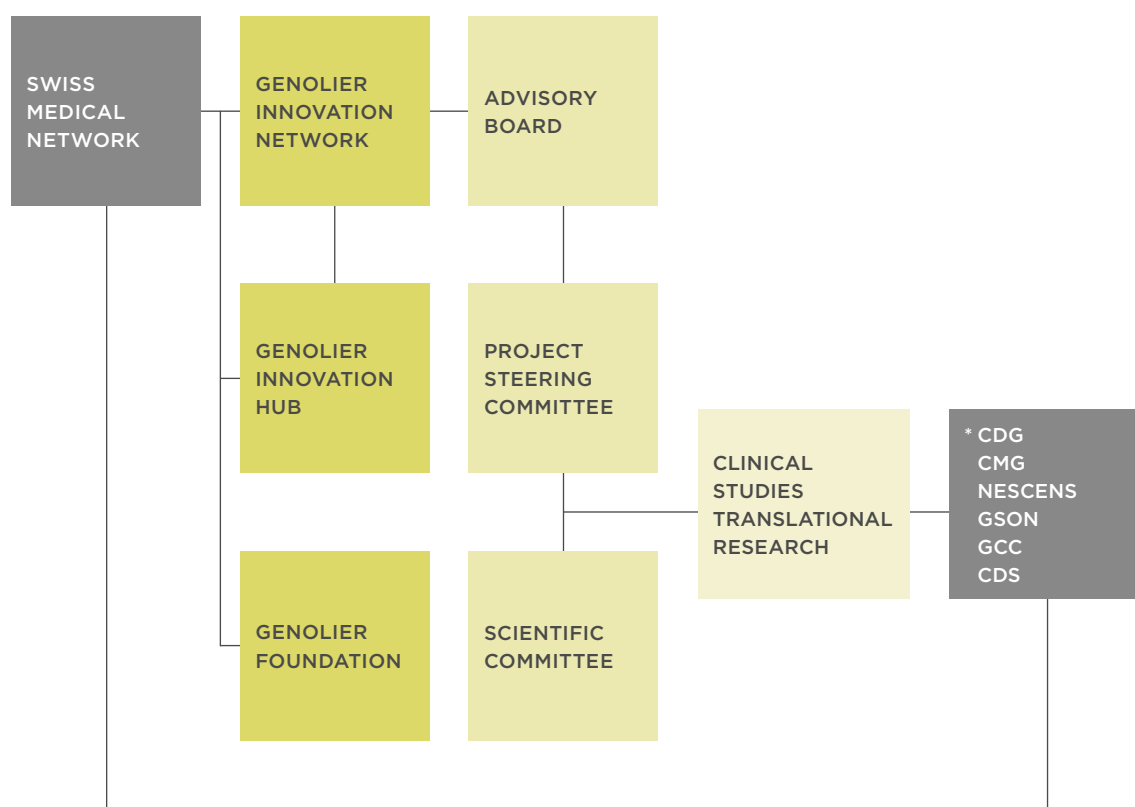
The Project Steering Committee is composed of physicians from various medical specialties, active in different Swiss Medical Network-sites, located in the three main linguistic regions of Switzerland:

- Medical Oncologist
- Radio-Oncologist
- Oncology-Surgeon
- Orthopedic Surgeon
- Ophthalmologist
- Cardiologist
- Radiologist

The dedicated liaison between Genolier Innovation Network's Advisory Board, the Project Steering- and Scientific Committee aims at facilitating the harmonization of development-strategies, plans and policies, with a view to achieving cooperation and concerted actions along the development of research programs conducted within Swiss Medical Network and other related organizations (all our research programs comply with the recommendations of the Swiss Academy of Medical Sciences and bio-ethical cantonal authorities).

Structure, bodies and research axes

GENOLIER HEALTHCARE CAMPUS



* CDG: Clinique de Genolier
 CMG: Centre Médical Genolier
 GSON: Genolier Swiss Oncology Network
 GCC: Genolier Cancer Center
 CDS: Centre du Sein

Research Governance and Scientific Bodies

Advisory Board

(as of April 2021, in alphabetical order)



Jacques Bernier
Chief Science Officer,
Genolier Innovation Network

Specialist in Radio-Oncology and Nuclear Medicine from the University of Liège in Belgium, Jacques Bernier is the Chief Science Officer of Genolier Innovation Network. From 2006 until 2019, he was Head of the Radiation Oncology Department at Clinique de Genolier and Medical Director of Centre d'Oncologie des Eaux-Vives in Geneva. He is the author/co-author of more than 140 scientific publications in peer-reviewed journals and more than 200 communications in national and international meetings.



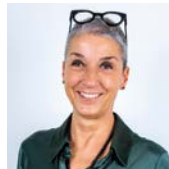
Stanley Hautdidier
Director,
Genolier Innovation Hub

An engineer by training and holding a master's degree in management, Stanley Hautdidier began his career with the world leader in endoscopy and operative integration as sales manager for integrated operating rooms on behalf of the Belgian, Luxembourg and Swiss subsidiaries. Subsequently, Stanley was CEO of an orthopedic company in Switzerland, in parallel with a consultant activity in the health sector.



Antoine Hubert
Delegate of the
Board of Directors,
Swiss Medical Network

Prior to acquiring a stake in Clinique de Genolier in 2002 and founding Swiss Medical Network in 2004, Antoine Hubert was mainly active in the property and real estate industry, has set up businesses and served as a director to several companies in various industries.



Patricia Muller-Hafner
Director Medical Marketing
Vaud,
Swiss Medical Network

Marketing-Specialist with a broad Product-Development background, strong focus on oncology and neurology.



Pr Walter Weder
Thoracic Surgery
Clinic Bethanien,
Privatklinik Bethanien

Professor of Surgery and former Director of the Thoracic Surgery Department at the University Hospital Zurich, Walter Weder currently leads the "Thoracic Surgery Clinic Bethanien". Professor Weder is the Founding President of the Swiss Society of Thoracic Surgery, the Lung transplant group of Swisstransplant and the President of the European Society of Thoracic Surgery (ESTS).

Project Steering Committee

(as of April 2021, in alphabetical order)

COORDINATORS



Dr Jacques Bernier
Chief Science Officer,
Genolier Innovation Network,
Specialist in Radio-Oncology,
Clinique de Genolier, Genolier



Pr Walter Weder
Specialist in Thoracic Surgery,
Privatklinik Bethanien, Zurich

MEMBERS



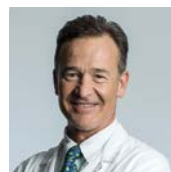
Pr Guido Garavaglia
Specialist in Orthopedic
Surgery and Traumatology,
Clinica Ars Medica, Gravesano



Pr Oscar Matzinger
President
Genolier Cancer Center,
Specialist in Radio-Oncology,
Clinique de Genolier, Genolier



Dr Volker Kirchner
Specialist in Medical Oncology,
Clinique de Genolier, Genolier



Dr Gabor Sütsch
Specialist in Cardiovascular
Diseases,
Privatklinik Bethanien, Zurich



Dr Antoine Leimgruber
Specialist in Nuclear Medicine,
Clinique de Genolier, Genolier



Pr Victor Valderrabano
Specialist in Orthopedic Surgery,
Schmerzklinik Basel, Basel



Pr Kaweh Mansouri
Specialist in Ophthalmology,
Swiss Visio, Lausanne



Dr Fabian Von Knoch
Specialist in Orthopedic Surgery,
Privatklinik Bethanien, Zurich

Scientific Committee

(as of April 2021, in alphabetical order)



Dr Matti Aapro

Member of the Board of Directors,
Genolier Cancer Center,
Specialist in Medical Oncology,
Clinique de Genolier, Genolier



Dr Christophe Cordier

European Board-certified
Genetic Counsellor,
Synlab, Lausanne



Dr Barbara Ankli

Specialist in Rheumatology
(Gout and crystal neuropathies),
Schmerzklinik Basel, Basel



Pr Guido Garavaglia

Specialist in Orthopedic
Surgery and Traumatology,
Clinica Ars Medica, Gravesano



Dr Jacques Bernier

Chief Science Officer,
Genolier Innovation Network,
Specialist in Radio-Oncology,
Clinique de Genolier, Genolier



Dr Philippe Glasson

President Scientific Committee
Swiss Medical Network,
Specialist in Internal Medicine
and Nephrology,
Clinique de Genolier, Genolier



Pr Peter Buchmann

Specialist for Surgery
and Intensive Medicine
(Visceral and thoracic surgery),
Privatklinik Bethanien, Zurich



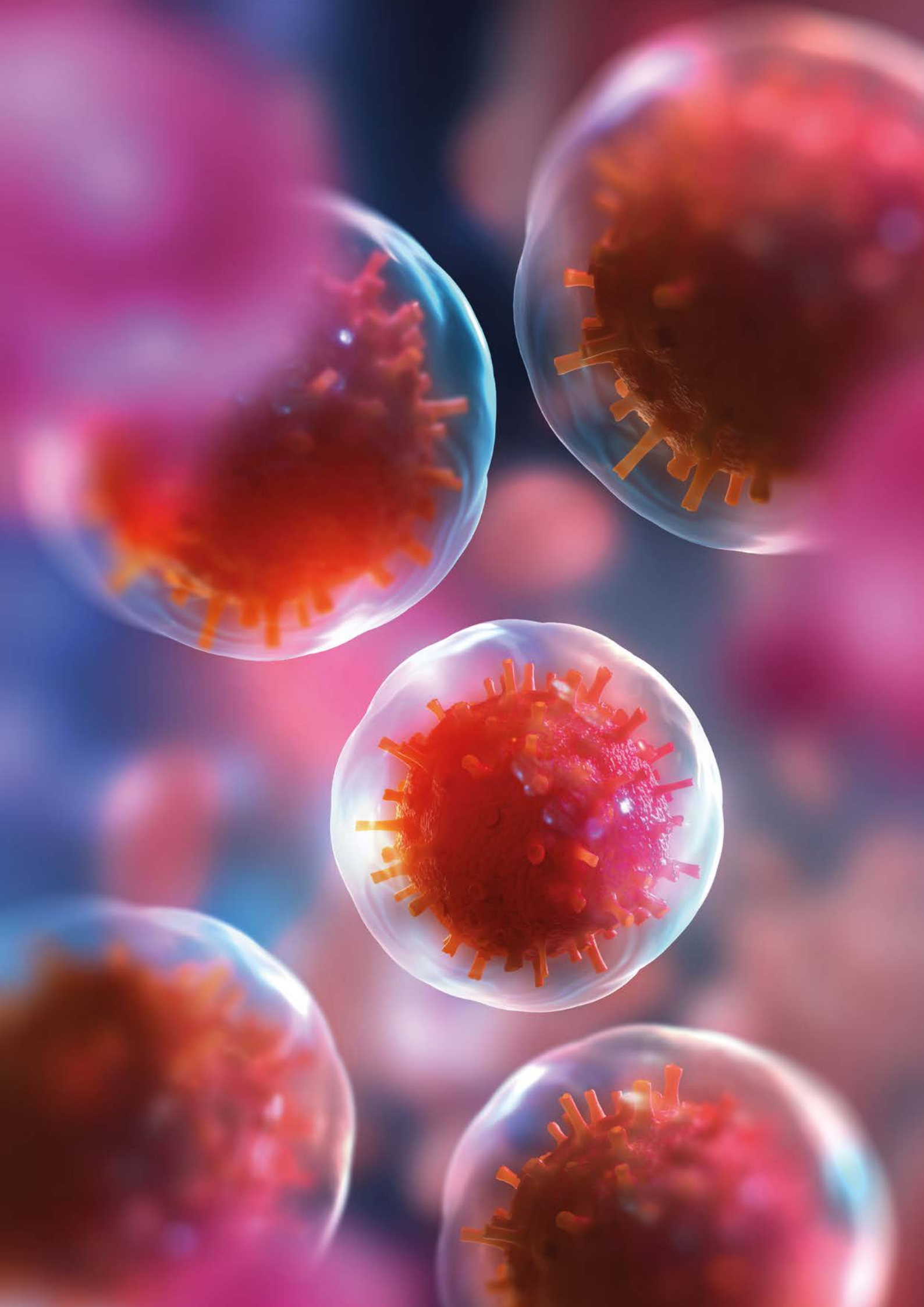
Pr Oscar Matzinger

President
Genolier Cancer Center,
Specialist in Radio-Oncology,
Clinique de Genolier, Genolier



Dr Daniel Christen

President Interdigest,
Consultant surgeon specializing
in Visceral surgery,
Privatklinik Bethanien, Zurich





Research Strategy

According to Swiss Federal Statistical Office and Swiss Health Observatory-reports, over 80% of people living in Switzerland perceive their health status as good. Life expectancy varies between 81 years for men and 85 years for women and approximately 70 years are mostly lived in good health. In later years, people tend, however, to have health issues and to suffer from chronic diseases, that often require intensive and long-term treatments.

Even though the overall health situation in Switzerland is perceived as being very good, the risk of developing cardiovascular diseases, cancer, diabetes, musculoskeletal disorders, respiratory diseases, dementia, mental illness etc. still persists, but could, by means of individual health behavior and conditions conducive to a healthy life, be further reduced.

Also in alignment with the national “Swiss Health 2030” focus, i.e.:

- Technological and digital change
- Demographic and social trends
- Preserving high-quality and financially sustainable healthcare provision
- Positively influencing the determinants of health

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Genolier Innovation Network covers **research-projects** on various **prevention, diagnostic** and **therapeutic activities**.

As an adaptation of “traditional” medical treatments to the patient’s individual molecular and genetic profile, **precision medicine** not only improves the ability to diagnose and treat disease, but enables furthermore an early disease-detection. Particular emphasis is put on treatment **outcome measurements** along the pathways, in order to further push **value-based medicine** promoted by Swiss Medical Network.

All together – a further step towards “total health”.



Research Domains

(in alphabetical order)

IMAGING

Interventional radiology

In the field of interventional radiology, Dr Pierre Bize (Clinique de Genolier) investigated the role of cryoablation in the management of various pathologies, such as benign mandibular tumors, extra-abdominal desmoid tumors and sacro-coccygeal chordomas. These various investigations demonstrated that, in selected patients, cryoablation is a safe, well-tolerated and effective therapeutic approach.

Nuclear Medicine

In 2020, Dr Jean-Pierre Papazyan (Clinique de Genolier) contributed to studies on determination of metabolic and cardio-vascular health, and on protocols comparing digital and conventional PMT-based PET/CT, in terms of image quality assessment.

IMMUNOLOGY – PUBLIC HEALTH

Dr Jacques Bernier (Clinique de Genolier) co-authored two Swiss Medical Network reports in the framework of COVID-19 research programs.

The first scientific study, commissioned in April 2020 by Swiss Medical Network, dealt with a SARS-CoV-2 sero-survey for a safe back-to-work program at Swiss Medical Network and AEVIS VICTORIA S.A. This public health report was based on the “Health Technology Assessment approach”, a tool to review health technologies and provide evidence of the value these technologies can deliver to patients and their families, health system stakeholders, and – more broadly – to society.

The second axis of research was a collaborative work between Swiss Medical Network and Synlab Suisse SA. It studied the sero-prevalence of anti-SARS-CoV-2 IgG antibodies in healthcare professionals working within the Network’s hospitals, and showed that combining a pre-test probability evaluation with a confirmation test algorithm enhances the robustness of post-test likelihood for reported individual results. The results of this clinical study were presented to Swiss Medical Network’s “Groupe de Coordination Médicale”, in Bern, on July 1, 2020 (J. Bernier et al.: “Use of serologic tests by Swiss Medical Network in the ‘back to work’ phase: critical appraisal”).

From April 2020 on, Jacques Bernier ensured the publication of the scientific Daily Bulletin of the “SMN COVID-19 Scientific Reporting”. The vocation of this daily bulletin is to offer access to prominent scientific publications on the natural history and management of the SARS-CoV-2 pandemic. He is also the author of a report on a critical appraisal of the clinical relevance of RT-PCR tests in the framework of this pandemic.

INTEGRATED CARE

Dr Jacques Bernier (Clinique de Genolier) actively participated to Kaiser Permanente (KP) International activities through interactive videoconferences, and in particular the workshop entitled “The Kaiser Permanente approach to care delivery: a story of integration and innovation” (April 7, 2020). With the collaboration of Karin Cooke, KP International Director, he also analyzed the actions taken by Kaiser Permanente in the US, in the framework of its fight against the Covid-19 pandemic, with particular emphasis on the potential transfer of KP’s “know how” in this domain to the integrated care program developed by Swiss Medical Network (internal report).

NEUROSURGERY

With the goal of improving the management of patients with spinal pathologies, Avaton Surgical Group (Dr John Michael Duff, Dr Rodolfo Maduri, Clinique de Genolier), is studying the clinical impact of new minimally invasive spinal surgery techniques, including imaging-guided transtubular techniques. There are three main fields of research conducted by the team in 2020:

1. Implementation of trans-tubular minimally invasive techniques in cervical disc hernia surgery.
2. Implementation of advanced radiological tracking techniques for the transtubular minimally invasive resection guided by images of spinal intradural tumors.
3. A clinical study on trans-tubular resection guided by tumor images, for intradural spinal diseases (IMTAR study – CER VD 172/15).

Dr Philippe Otten (Clinique Générale Ste-Anne, Fribourg) contributed to a prospective, controlled, multicenter study to evaluate the association between appropriate use of surgery and postoperative outcome in degenerative spondylolisthesis. This issue is of particular relevance since Swiss Medical Network recently embarked on integrated care pathways, including analytical processes on research outcome measurements. Another field of research was the role of surgery in case of brain metastasis in post-chemotherapeutic status.

ONCOLOGY

Oncology – Health Outcome

In 2020, Dr Jacques Bernier (Clinique de Genolier) was among the McMaster GRADE Centre researchers, who developed 'Health Outcome Descriptors' for standardizing descriptions of health outcomes and overcoming these problems to support the European Commission Initiative on Breast Cancer (ECIBC) Guideline Development Group (GDG). This European program aims to determine which aspects of the development, content, and use of health outcome descriptors for breast cancer are valuable to guideline developers.

Medical Oncology

In 2020, Dr Matti Aapro (Clinique de Genolier) published 20 peer-reviewed articles in various domains of medical oncology. His numerous research programs in geriatric oncology, breast cancer management and supportive care bear witness to his experience in clinical research protocols and educational activity. Besides his position as President of the European Cancer Organisation, an umbrella organization representing 34 professional societies and 20 patient groups (www.europeancancer.org), he is President of Sharing Progress in Cancer Care, a non-profit organization (www.spcc.net).

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With Innomedica Holding AG staff members, Dr Matti Aapro (as Advisory Board member) and Dr Jacques Bernier (as Swiss Medical Network Chief Science Officer) also took part to the preparatory platform of a phase II clinical trial investigating the role of a new cancer drug, Talidox®. Based on InnoMedica's liposomal transport system, this drug is being investigated in patients with advanced and metastatic cancers.

As regards translational research, the collaboration between the Réseau Romand d'Oncologie and the medical oncology team of Clinique de Genolier was further developed, mainly in the field of the biomolecular approach to cancer treatment for selected patients.

Radio-Oncology: Medical Physics

Shelley Bulling (Clinique de Genolier and Centre d'Oncologie des Eaux-Vives, Geneva) contributed to a scientific article based on the compilation of an atlas aimed to optimize the contouring of the heart and the coronary vessels in patients with breast cancer, in order to reduce the toxicity of irradiation in this patient population.

Surgery

At Privatklinik Bethanien, the outstanding scientific contribution of Pr Walter Weder to advances in Thoracic Surgery is acknowledged at an international level.

Dr Daniel Christen, President of the Interdisciplinary Gastroenterological Surgical Team (Interdigest), Privatklinik Bethanien, develops a regional network of surgeons, oncologists and gastroenterologists, working closely with pathologists, radiologists and other experts on specific issues. Their main objective is a real-time implementation of the most recent scientific advances in the domain of the digestive tract malignancies.

OPHTHALMOLOGY

Pr Kaweh Mansouri and Pr André Mermoud (Swiss Visio, Lausanne) develop research on diagnosis and treatment of glaucoma, following three main tracks:

1. Therapy: personalized (precision) surgery based on intra-operative imaging using Optical Coherence Tomography (OCT) and angiography;
2. Value-based medicine and outcome measurements: e.g. by weighting efficacy in individual patients (# of post operative consultations vs. # of intraocular pressure outcomes); development of longitudinal studies;
3. Artificial intelligence tools: monitoring of eye pressure using intraocular captors: ongoing development in collaboration with EPFL, start-ups, and University of Colorado, Denver and University of California, San Diego.

In addition, the Swiss Visio and Swiss Glaucoma Research Foundation's glaucoma imaging, surgery and laser databases include at present well over 2500 cases.

A number of events are also organized by the glaucoma team including scientific webinars and international conferences. In 2020, the glaucoma team has published 40 papers in prestigious peer-reviewed international journals, putting Swiss Visio under the Top 5 glaucoma research centers worldwide.

Pr Mansouri took part as a collaborating center in two articles published in the renowned Lancet Global Health. Public health services around the world are failing to meet the objective to reduce preventable vision loss. Researchers found that the leading cause of blindness was cataract, which affects 15 million people, or about 45% of the 33.6 million cases. It has also caused severe visual impairment in 78 million people and can be treated with surgery. In the framework of the American Academy of Ophthalmology, Pr Mansouri also published a reference manual on the detection of glaucoma progression via OCT: Focal Points: "Optical Coherence Tomography for the Management of Glaucoma". Thanks to the high 2020 ranking of Pr K. Mansouri among the best glaucoma specialists worldwide ("Expertscape's Leaders in Glaucoma"), Swiss Visio climbed to place 15 on this prestigious list and first in Europe.

ORTHOPEDIC SURGERY

Pr Guido Garavaglia, Head of Teaching and Research at Clinica Ars Medica in Gravesano, is involved in several projects of the Geneva Arthroplasty Registry. His main research focus is radiographic analysis and outcome measurements in orthopaedics. He supervises the introduction of Patient-Reported Outcome Measures (PROMS) at the Clinica Ars Medica.

Dr Laurence Grüber (Clinique Générale Ste-Anne, Fribourg) published two studies on hand surgery, reporting on joint replacement and movement analysis, with particular emphasis on post-operative outcome.

Pr Victor Valderrabano (Schmerzklinik, Basel) co-authored scientific contributions covering a meta-analysis on autologous matrix-induced chondrogenesis (AMIC) for chondral defects in the talus, and various articles on neglected iatrogenic flexor hallucis longus tendon rupture after Haglund's endoscopic surgery, and management of varus ankle osteoarthritis.

Dr Michael Wettstein (Clinique de Genolier) was part of a research team reporting on a prospective multicenter study, that assessed the clinical benefit drawn from labral repair during arthroscopic treatment of femoro-acetabular impingement. His clinical research programs in various orthopedic domains as reverse peri-acetabular osteotomy, hip preservation surgery techniques, and hip micro-instability were also the subject of textbook chapters.

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OUTCOME RESEARCH - VALUE-BASED MEDICINE

Dr Jacques Bernier (Clinique de Genolier) was invited to participate as an expert in two national scientific advisory boards regarding the implementation of outcome research in clinical practice. The first one, organized by the relevant unit of Novartis, covered the issue of Systems Approach in chronic diseases, with particular emphasis on the role of patient journey science, predictive modeling in high-risk patients at early stage of disease. The mission of the second advisory board was to set up the bases of the Basel's DayOne Value-Based - VBH Conference.

As regards outcome measurements, a pillar of the current and future initiatives of the Genolier Innovation Network in the Swiss Medical Network clinical practice, Dr Jacques Bernier developed in 2020 an active participation to the International Consortium for Health Outcome Measurements - ICHOM activities.

Finally, in the framework of the development of integrated care in Switzerland, he participated, in September 2020, to the 2-day Healthcom event entitled "Kooperationen in der Gesundheitsbranche: Das 'Neue Normal' in Richtung Population Health?", organized at the Gottlieb Duttweiler Institute, Rüschlikon.

PREVENTIVE HEALTH

At Nescens Clinique de Genolier and Laboratoires Genolier, Pr Jacques Proust worked on a research-program articulated around the production and development of new products from the Nescens cosmeceutics portfolio, including:

- Senolytic serum designed to eliminate senescent epidermal cells able to promote rejuvenation of skin structures;
- "Booster" serum containing high concentrations of niacinamide and dexpanthenol, compounds involved in maintenance and molecular repair activities, and promoting the expression of genes involved in tissue repair;
- "Booster" serum containing high concentrations of bakuchiol and ascorbyl tetraiso-palmitate whose action, in addition to its anti-oxidant properties, is to stimulate the production of collagen and elastin;
- Serum for autologous use and containing exosomes obtained during the culture of mesenchymatous stem cells taken during lipoaspiration.

These exosomes contain the main elements of intercellular communication and their application induces the same positive effects as the injection of mesenchymatous stem cells on the renewal and rejuvenation of the epidermis.

QUALITY ASSURANCE

As members of the ANQ (Swiss National Association for Quality Development in Hospital), the various teams of orthopedic surgery active at Swiss Medical Network enter since 2016 data into the SIRIS register (Registre Suisse des Implants):

- Activity volumes relevant to implanted total primary hip and knee prostheses
- Two-year revision rates for these primary total prostheses

The yearly number of implanted hip prostheses (25 implants per surgeon) is actually higher than the Swiss average, which puts Clinique de Genolier in the safe zone. As far as implanted knee prostheses are concerned, Clinique de Genolier matches Swiss average.

The data analysis, carried out by Dr Bernard Bédât and Mrs Marie Lombard, also showed that the two-year revision rate of the primary total hip prostheses was below Swiss average; the corresponding rate for knee prostheses revision was slightly but not significantly above National risks for surgical revision (hip: infection, fracture and dislocation; knee: infection and fracture). At Clinique de Genolier, outcome measurements showed good quality indices regarding surgery and follow-up procedures, as well as advices given to patients for rehabilitation (www.anq.ch).

UROLOGY

In Geneva, the Générale-Beaulieu urology team (Dr Georges-Antoine de Boccard, Dr Martina Martins, Dr Stefano Regusci, Dr Charles-Henry Rochat) developed several axes of research with particular emphasis on prostate cancer and best practice in the management of vesico-vaginal fistula repair. As regards prostate cancer, the medical team reported on the role of multiparametric MRI for detection and localization of prostate cancer depending on the affected region. With respect to the management of vesico-vaginal fistula, Dr Charles-Henry Rochat's team developed research programs including robotic-assisted repair (in the framework of a Consensus Report from the European Association of Urology Robotic Urology Section Scientific Working Group for Reconstructive Urology), as well as prognostic factors and socio-economic aspects of this pathology and its therapeutic management. In October 2020, Dr Charles-Henry Rochat, member of the Fistula Group, was awarded the Alumnus Prize of the University of Geneva at the Dies Academicus ceremony.

Main research domains

(in alphabetical order)

1 IMAGING

Clinique de Genolier

2 IMMUNOLOGY - PUBLIC HEALTH

Clinique de Genolier

3 INTEGRATED CARE

Clinique de Genolier

4 NEUROSURGERY

Clinique de Genolier

Clinique Générale Ste-Anne

5 ONCOLOGY

Centre d'Oncologie des Eaux-Vives

Clinica Sant'Anna

Clinique de Genolier

Clinique Générale-Beaulieu

Clinique Générale Ste-Anne

Privatklinik Bethanien

6 OPHTHALMOLOGY

Swiss Visio Montchoisi

7 ORTHOPEDIC SURGERY

Clinica Ars Medica

Clinique de Genolier

Clinique Générale Ste-Anne

Privatklinik Bethanien

Schmerzlinik Basel

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Swiss Medical Network sites with ongoing research projects

8 OUTCOME RESEARCH - VALUE-BASED MEDICINE

Clinica Ars Medica
Clinique de Genolier
Clinique de Montchoisi

9 PREVENTIVE HEALTH

Clinique de Genolier

10 QUALITY ASSURANCE

Clinique de Genolier
Nescens Clinique de Genolier

11 UROLOGY

Clinique de Genolier
Clinique Générale-Beaulieu
Privatklinik Bethanien



BASEL

Schmerzklinik Basel



FRIBOURG

Clinique Générale Ste-Anne



GENEVA

Clinique Générale-Beaulieu
Centre d'Oncologie des Eaux-Vives



GENOLIER

Clinique de Genolier
Nescens Clinique de Genolier



LAUSANNE

Clinique de Montchoisi
Swiss Visio Montchoisi



TICINO

Clinica Ars Medica, Gravesano
Clinica Sant'Anna, Sorengo



ZURICH

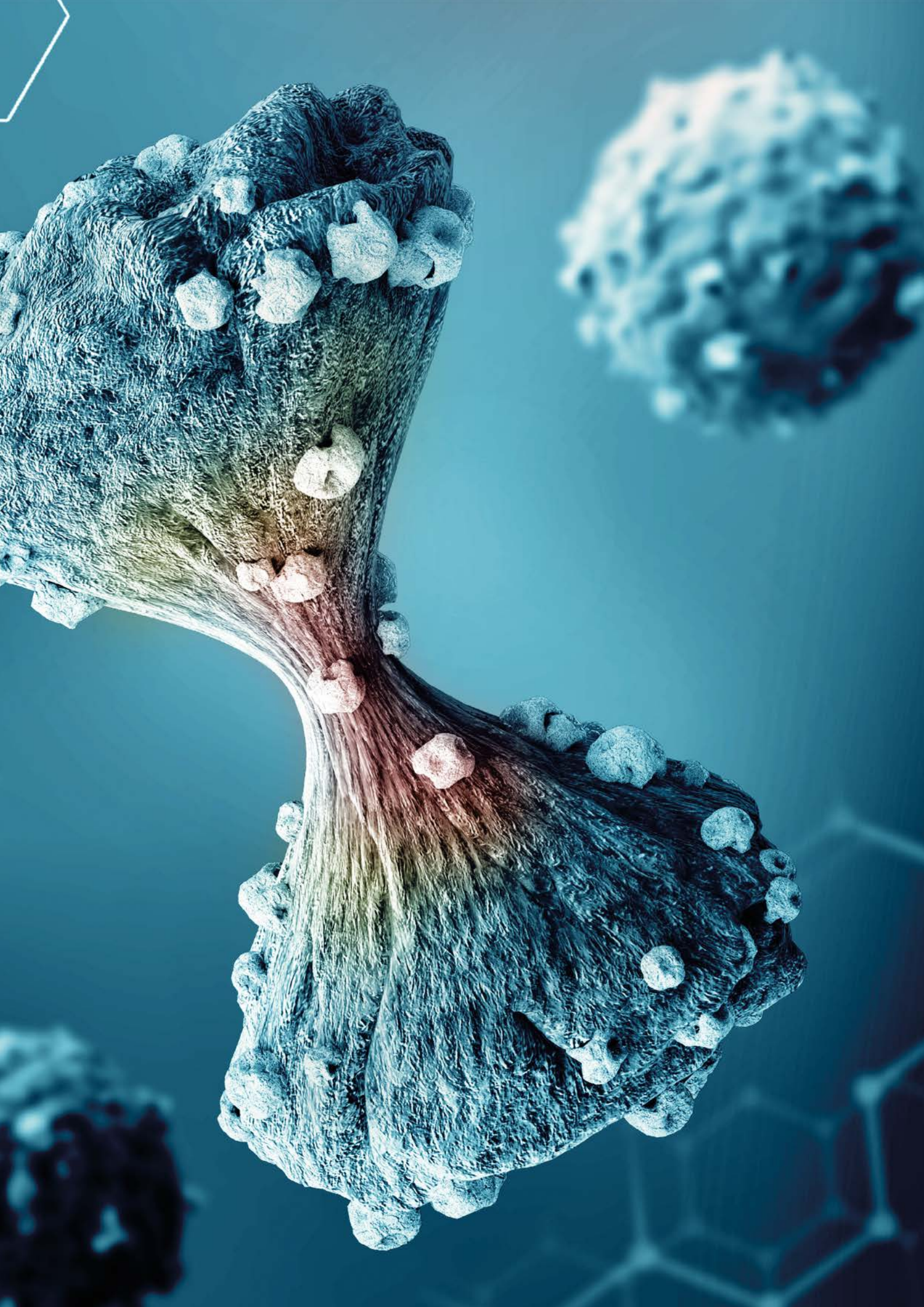
Privatklinik Bethanien

Research Protocols

Oncology (by organs)

STUDY NAME	CLINICAL TARGETS
BREAST INTRAOPERATIVE RADIOTHERAPY - IORT	
Etude sur les patientes bénéficiant d'une radiothérapie intra-opératoire (IORT) à la Clinique de Genolier + Hôpitaux Universitaires de Genève.	Breast
PREVENT	
Etude suisse, multicentrique, randomisée, placebo contrôlée, sur l'utilisation préventive de la prégabaline chez les patientes à haut risque de développer des douleurs persistantes après une chirurgie de cancer du sein.	Breast
RIB-ELLE	
A non-interventional study to assess the safety and efficacy of RIBociclib in combination with an aromatase inhibitor (letrozole, anastrozole, exemestane) in the Swiss advanced breast cancer population.	Breast
SAKK 23/16 - TAXIS	
Tailored AXillary Surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer. A multicenter randomized phase III Trial.	Breast
SAKK 95/17	
A 24 weeks activity program in patients with early breast cancer receiving aromatase inhibitor therapy. A multicenter randomized phase III Trial.	Breast
SAKK 23/18 - VISION I	
Vacuum assisted biopsy Immediately before Surgery as an Intra- or pre-Operative surrogate for patient response to Neoadjuvant chemotherapy for breast cancer (VISION I).	Breast

STUDY NAME	CLINICAL TARGETS
SAKK 96/12 – REDUSE Prevention of symptomatic skeletal events with Denosumab administered every 4 weeks versus every 12 weeks – A non-inferiority Phase III Trial.	Breast Prostate
SAKK 08/15 – PROMET Multicenter, randomized Phase II Trial of salvage radiotherapy +/- Metformin for patients with prostate cancer after prostatectomy.	Prostate
SAKK 41/13 – ASPIRINE / EORTC 1534 Traitement complémentaire à l'aspirine lors du cancer du côlon. Une étude randomisée en double aveugle et contrôlée par placebo de phase III.	Colon
OPERA Essai clinique européen phase III comparant en association avec une chimio-radiothérapie néoadjuvante une escalade de dose d'irradiation distribuée par 2 techniques: irradiation externe vs irradiation endocavitaire utilisant une RT de contact (Rx 50kV) chez des patients présentant un adénocarcinome rectal T2-T3a-b < 5cm de diamètre rectum inférieur ou moyen.	Rectum
BAZEDOXIFENE Bazedoxifene, a selective estrogen receptor modulator clinically available for the treatment of osteoporosis, has shown to be an effective GP130/STAT3 signaling inhibitor through in vitro and small animal studies.	Pancreatic and gastric tumors
NIVO-71 REGISTRY A registry for patients with progressing metastatic solid tumor infiltrated by CD8+ T cells and receiving Nivolumab Off-label in the Romand Network of Oncology (RRO).	All solid malignancies



Oncology protocols

Breast cancer

BREAST INTRAOPERATIVE RADIOTHERAPY – IORT: STUDY OVERVIEW

- Patients entered into this study are those presenting with favorable breast cancer.
- This clinical study investigates the role of a new irradiation approach, called intra-operative radiotherapy (IORT), a technique that allows the integration of a single session of radiotherapy at the time of surgery.
- The study aims at demonstrating that a single session of IORT delivered in a few minutes is as efficacious as conventional postoperative radiotherapy, which necessitates 3 to 6 weeks of treatment.
- Should this equivalence of efficacy be confirmed, the use of IORT would then be considered as a valid alternative of therapeutic management in a significant number of patients presenting with favorable breast cancer.

Patient population

Inclusion criteria for exclusive IORT are as follows : histologically proven, invasive or intraductal (< 2 m); cT1 or size < or = 25 mm in diameter at imaging (MRI mandatory); no nodal infiltration; post-menopausal status; tumor(s) amenable to conservative breast surgery (BCS) including multifocal tumors with close vicinity, and bilateral carcinomas; no contra-indication to radiotherapy; nipple skin sparing mastectomy (eligible for IORT to the nipple-areolar complex only (NAC)); unifocal, small local recurrence following BCS (ad-hoc evaluation).

Eligibility criteria for partial IORT include pre- or peri-menopausal status; presence of unfavourable risk factors such as perineural or lymphovascular infiltration; limited axillary nodal invasion (N1).

Background and Rationale

Breast cancer patients presenting with low- and intermediate risk disease might benefit from the application of the partial breast irradiation concept. As part of this strategy, intra-operative radiotherapy can significantly reduce the overall treatment time with respect to postoperative irradiation.

Objective(s)

The objective of this study was first to analyze the efficacy results in a cohort of breast cancer patients presenting with favorable risk factors and treated with breast conserving surgery and IORT. This analysis also included the assessment of the incidence and severity of both, acute and late effects.

Study Title

Breast cancer intraoperative radiotherapy: outcome analysis in patients with favourable and intermediate risk disease.

Clinical Phase

Retrospective analysis.

Sponsor

Breast Unit, Clinique de Genolier.

Coordinating investigators

J. Bernier, M. Kohlik,
P-A Brioschi, J-C Horiot.
Breast Unit Clinique de
Genolier, CH-Genolier.

Breast cancer

PREVENT: STUDY OVERVIEW

- Patients entered into this study are those presenting with high-risk breast cancer and treated by surgery.
- Persistent postsurgical pain occurs in more than 30% of patients undergoing breast cancer surgery.
- This clinical study aims at determining whether pregabalin, a drug with analgesic and anxiolytic activities, may reduce the incidence of persistent postsurgical pain.
- Should a significant analgesic effect of pregabalin be demonstrated by this study, the administration of this drug would be strongly recommended in the future for breast cancer patients at risk of developing post-surgical, chronic pain syndrome.

Study Title

Swiss multi-center, randomized, placebo controlled trial of pregabalin for prevention of persistent pain in high risk patients undergoing breast cancer surgery.

Clinical Phase

Clinical phase III study.

Sponsor-Investigator

B. Rehberg-Klug, CH-Geneva.

Patient population

High-risk patients undergoing breast cancer surgery.

Background and Rationale

Persistent postsurgical pain occurs in more than 30% of patients undergoing breast cancer surgery. Evidence that gabapentinoids such as pregabalin may reduce the incidence of persistent post-surgical pain is ambiguous, potentially because in previous trials prophylactic treatment was administered to every patient undergoing surgery. The patients at low risk of long-term pain are exposed to side effects without much benefit to expect.

Objective(s)

The PREVENT study has two aims:

- Validating or refuting the utility of pregabalin to prevent long-term postoperative pain in patients at high risk of persistent pain after breast cancer surgery.
- Analyzing how side-effect information influences treatment tolerance.

In addition, genetic material will be collected for a later genetic association analysis on acute and chronic post-surgical pain.

Breast cancer

RIB-ELLE: STUDY OVERVIEW

- The patients entered into this study are post-menopausal female patients (≥ 18 years old), with a diagnosis of HR+/HER2-negative advanced breast cancer.
- Endocrine (hormonal) therapy has been the backbone of HR+/HER2- negative advanced breast cancer treatment, nevertheless its efficacy is limited.
- The primary objective is to analyze the potential advantages of the addition of ribociclib - a CDK4/6 inhibitor - to an aromatase inhibitor in these patients in comparison with the endocrine therapy alone.

Patient population

The study will enroll 200 adult post-menopausal female patients (≥ 18 years old), with a diagnosis of HR+/HER2-negative advanced breast cancer that will be treated with ribociclib and an aromatase inhibitor.

Background and Rationale

Endocrine (hormonal) therapy has been the backbone of HR+/HER2- negative advanced breast cancer treatment, nevertheless its efficacy is limited.

A recent clinical study showed that in postmenopausal women with HR+/HER2-negative advanced breast cancer who had received ribociclib, a CDK4/6 inhibitor, plus letrozole versus placebo plus letrozole, showed that a 44% relative risk reduction was evident in the hazard rate of progression /death in favor of ribociclib plus letrozole.

Objective(s)

The primary objective is to analyze time to treatment failure (TTF) for the initial endocrine based treatment with ribociclib plus an aromatase inhibitor in patients with HR+/HER2-negative advanced breast cancer in a real world patient population (Switzerland).

Study Title

RIB-ELLE: A non-interventional study to assess the safety and efficacy of RIBociclib in combination with an aromatase inhibitor (letrozole, anastrozole, exemestane) in the Swiss advanced breast cancer population.

Clinical Phase

Clinical non-interventional study.

Sponsor-Investigator

Dr. Nadine Pasche, Novartis Pharma Schweiz AG.

Breast cancer

SAKK 23/16 – TAXIS: TRIAL OVERVIEW

- Patients entered into this trial are those presenting with breast cancer, with positive axillary nodes.
- This clinical study investigates the role of a new surgical approach, called tailored axillary surgery (TAS), an innovative technique that aims at selectively removing the positive lymph nodes.
- The study compares this new surgical approach, which is likely to reduce the surgery side effects, to conventional axillary dissection.
- Should TAS be as efficacious as conventional surgery in terms of disease control, the use of this innovative approach would then improve the quality of life of a significant number of breast cancer patients with positive nodes in the axilla.

Trial Title

SAKK 23/16 / IBCSG 57-18/ABCSG-53. Tailored AXillary Surgery with or without axillary lymph node dissection followed by radiotherapy in patients with clinically node-positive breast cancer (TAXIS).

Clinical Phase

Clinical trial phase III.

Sponsor

Swiss Group for Clinical Cancer Research (SAKK).

Coordinating investigator

W.P. Weber, CH-Basel.

Patient population

The TAXIS trial will evaluate the optimal treatment for breast cancer patients with confirmed nodal disease at first diagnosis in terms of surgery and radiotherapy.

Background and Rationale

The removal of all lymph nodes in the armpit through conventional axillary dissection has been standard care for all patients with breast cancer for almost a century. In the nineties, the sentinel lymph node (SLN) procedure, which involves the selective removal of the first few lymph nodes in the lymphatic drainage system, was introduced in clinical practice. Today, conventional axillary dissection is still performed on many women with breast cancer that has spread to the nodes. It is the cause for relevant morbidity in the form of lymphedema, impairment of shoulder mobility, sensation disorders and chronic pain in as much as one third of all women undergoing the procedure. The TAXIS trial will evaluate the optimal treatment for breast cancer patients with confirmed nodal disease at first diagnosis in terms of surgery and radiotherapy.

Objective(s)

TAXIS will investigate the value of tailored axillary surgery (TAS), a new technique that aims at selectively removing the positive lymph nodes. TAS is a promising procedure that may significantly decrease morbidity in breast cancer patients by avoiding surgical overtreatment.

The main objective of the trial is to show that tailored axillary surgery (TAS) and axillary radiotherapy (RT) is non-inferior to axillary lymph node dissection (ALND) in terms of disease-free survival of breast cancer patients with positive nodes.

Breast cancer

SAKK 95/17: TRIAL OVERVIEW

- The patients entered into this study are patients with early breast cancer receiving aromatase inhibitor (AI) therapy.
- Common side effects of AI therapy are, among others: joint pain, muscle pain, stiffness.
- The primary objective is to investigate if a simple outdoor walking intervention can prevent the occurrence of muscle or joint pain/stiffness in breast cancer patients treated with aromatase inhibitors.

Patient population

Patients with early breast cancer receiving aromatase inhibitor therapy.

Background and Rationale

After tumor removal, patients with hormone receptor positive breast cancer tumors often receive adjuvant endocrine treatment, with the use of an aromatase inhibitor (AI) being standard of care in the population of postmenopausal women. Common side effects of AI therapy are joint pain, muscle pain, stiffness, fatigue, hot flashes, and weight gain. Arthralgia and/or myalgia can result in lower physical activity and can negatively influence quality of life (QoL). In addition, muscle or joint pain/stiffness are among the main reasons for non-compliance and discontinuation of AI therapy. Since AI therapy is usually administered for 5 and sometimes even 10 years, this is a major clinical challenge.

For breast cancer patients undergoing AI therapy, physical activity can provide potential benefit by reducing muscle/joint pain and fatigue and can thus improve QoL. The preventive effect of physical activity on AI side effects, however, remains elusive. In addition, activity programs to reduce AI side effects have so far mostly been rather complex. The intervention planned in this study begins at the start of AI therapy, is simple and should therefore be executable under real life conditions, and has the potential to result in sustained alterations in life style. It consists of a simple, home-based intervention aiming at achieving "brisk recreational outdoor walking (moderate intensity) continuously for at least 30 minutes a day, with the aim to take at least 3000 steps, on 5 days per week".

Objective(s)

The primary aim is to investigate if outdoor walking can prevent the occurrence of muscle/joint pain or stiffness.

Furthermore, this trial will assess the effect of physical activity on symptom burden in general and quality of life in patients receiving adjuvant AI therapy.

During the follow-up phase, the trial will assess whether this intervention leads to a sustained change in lifestyle regarding activity, less pain, and better treatment adherence in the intervention group.

Trial Title

A 24 weeks activity program in patients with early breast cancer receiving aromatase inhibitor therapy.

Clinical Phase

A multicenter randomized phase III trial.

Sponsor

Swiss Group for Clinical Cancer Research (SAKK).

Coordinating investigators

PD Dr. Dr. med. Friedemann Honecker, ZeTuP, St. Gallen; Nicolette Hoefnagels, MSc, ZeTuP, CH-St. Gallen.

Breast cancer

SAKK 23/18 – VISION I: TRIAL OVERVIEW

- Patients entered into this trial are those presenting with luminal B, ER<10%, cT1c-cT2c breast cancer, with (near) complete radiological response after neo-adjuvant chemotherapy (NAC).
- As NAC induces different response patterns, radiologic imaging is not sufficiently accurate in predicting residual disease. This clinical study investigates the sensitivity of vacuum-assisted biopsy (VAB) through the possibility of obtaining tissue of the former tumor center that could contribute more reliably to detect any residual tumor or respectively, rule out residual disease.
- The main objective of the trial is to determine the diagnostic accuracy of the post-NAC VAB in determining pCR, compared to open surgery.
- Should vacuum-assisted biopsy be more sensitive than open surgery to detect pCR after neo-adjuvant chemotherapy, this former technique should be considered as standard approach in the patient population mentioned above.

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Trial Title

Vacuum assisted biopsy
Immediately before Surgery
as an Intra- or pre-Operative
surrogate for patient
response to Neoadjuvant
chemotherapy for breast
cancer (VISION I).

Patient population

Patients with unifocal, histologically confirmed invasive breast cancer with immunohistochemistry luminal B type (with or without overexpression or amplification of the HER2 receptor) and all ER negative (ER < 10%) breast cancers. Initial tumor size larger than 1 and less than 5 cm (cT1c to cT2), any N, M0. Following neoadjuvant chemotherapy resulting in a radiological complete response or near complete response on MR-Imaging.

Clinical Phase

A multicenter prospective
feasibility trial. Clinical trial
with other health intervention.

Sponsor

Swiss Group for Clinical
Cancer Research (SAKK).

Coordinating investigator

C. Tausch, CH-Zürich.

Background and Rationale

Neoadjuvant chemotherapy (NAC) has lately become common practice in the primary treatment of breast cancer. The use of modern NAC regimens lead to a complete pathologic remission (pCR) of the tumor in more than 50% in aggressive tumor types.

In general, it is difficult to predict pCR in the absence of invasive surgical techniques, as it depends on several factors such as biological subtype, the used chemotherapy regimen and anatomic stage. As NAC induces different response patterns, radiologic imaging is not sufficiently accurate in predicting residual disease. Because of this uncertainty, surgery (and the standardized assessment of resected tissue) is so far the only valid option to either ascertain complete response or to remove the complete residual disease.

Vacuum-assisted biopsy (VAB) with the possibility of obtaining tissue of the former tumor center could contribute more reliably to detect any residual tumor or respectively, rule out residual disease. Ultrasound (US) or mammographically (MG) guided VAB will be used in this trial in order to detect residual tumor lesions in patients with radiological complete response (rCR) after NAC.

Objective(s)

The main objective of the trial is to determine the diagnostic accuracy of the post-NAC VAB in determining pCR compared to open surgery.

Breast and Prostate cancer

SAKK 96/12 - REDUSE: TRIAL OVERVIEW

- Patients entered into this study are those presenting with bone metastases from castration resistant prostate cancer or from breast cancer.
- Denosumab, a monoclonal antibody, has a high activity in preventing skeletal related events. Although denosumab is generally well tolerated, severe toxicities as marked hypocalcemia can be observed after the administration of this drug.
- The main objective is to compare two modalities of Denosumab administration, namely every month vs every three months, in these two patient populations.
- Should a dose reduction of this drug show equivalent efficacies, patients could be treated with less toxicities, resulting in a better quality of life.

Patient population

Patients with bone metastases from castration resistant prostate cancer or from breast cancer.

Background and Rationale

Based on their ability to inhibit osteoclast activity, biphosphonates have been used for more than a decade to delay the onset and to reduce the incidence of skeletal related events (SREs) in people with breast and prostate cancer. Traditionally, SREs were defined as a pathologic fracture, spinal cord compression, requirement for radiation therapy or surgery to bone or change in antineoplastic therapy to treat bone pain. Denosumab, a human monoclonal antibody against RANKL, entered the field and three phase III studies have shown a higher activity in preventing SREs as compared with zoledronic acid without impact on disease progression or death. Although generally well tolerated, severe hypocalcemia (corrected serum calcium <1.75 mmol/L) was reported to occur in 3.1% of patients treated with denosumab (versus 1.3% of patients treated with zoledronic acid), and even fatal and prolonged cases have been reported. The impact of dose reduction on SREs has therefore to be investigated.

Objective(s)

The main objective is to establish that denosumab 120 mg given every 12 weeks is non-inferior to denosumab 120 mg given every 4 weeks, in patients with bone metastases from castration resistant prostate cancer or from breast cancer.

Trial title

SAKK 96/12. Prevention of symptomatic skeletal events with denosumab administered every 4 weeks versus every 12 weeks.

Clinical phase

A non-inferiority phase III trial.

Sponsor

Swiss Group for Clinical Cancer Research (SAKK).

Coordinating investigator

R. von Moos. Kantonsspital Graubünden, CH-Chur.

Prostate cancer

SAKK 08/15 – PROMET: TRIAL OVERVIEW

- Patients entered into this study are those presenting with prostate cancer recurring after prostatectomy and treated with radiotherapy.
- A number of pre-clinical studies have emphasized a specific interaction between metformin, an anti-diabetic drug, and radiation therapy, to enhance tumor cell killing.
- The main objective of the trial is to explore the efficacy of the addition of metformin to radiotherapy.
- Should metformin improve disease control in this patient population, the addition of this drug to radiotherapy would be highly recommended in case of local failure after prostatectomy.

Trial title

PROMET - Multicenter, randomized phase II trial of salvage radiotherapy +/- metformin for patients with prostate cancer after prostatectomy.

Clinical phase

Multicenter, randomized phase II trial.

Sponsor

Swiss Group for Clinical Cancer Research (SAKK).

Coordinating investigator

D.M. Aebersold. CH-Bern.

Patient population

Patients with prostate cancer after prostatectomy.

Background and Rationale

A substantial body of evidence based on laboratory and animal data supports that a specific interaction between metformin and radiation therapy exists through various mechanisms of action. Thus, metformin may represent an effective and inexpensive means to improve clinical outcomes with an optimal therapeutic ratio.

PROMET is a follow-up study of the SAKK 09/10. The latter is a randomized phase III trial addressing dose-escalation to the prostate fossa of patients with biochemical relapse after prostatectomy. PROMET maintains similar inclusion criteria and endpoint definitions of the SAKK 09/10, therefore outcome data can be properly compared between these two studies.

Objective(s)

The main objective of the trial is to explore the efficacy of SRT plus metformin compared to SRT in the endpoint of time to progression after prostatectomy failure.

Colo-rectal cancer

SAKK 41/13-ASPIRIN: TRIAL OVERVIEW

- Patients entered into this study are those presenting with colon cancer, at an intermediate or advanced stage of disease, and in whom a gene mutation, namely PIK3CA, is identified.
- Many clinical studies have provided evidence for a protective effect of aspirin on colorectal cancer.
- The trial objective is to demonstrate that the daily administration of aspirin for a 3-year period can prolong the survival of these patients.
- Should the efficacy of aspirin be confirmed, the use of aspirin would be strongly recommended in colon cancer patients with PIK3CA gene mutation.

Patient population

PIK3CA mutated colon cancer patients.

Background and Rationale

Many observational and even randomized studies have provided evidence for a protective effect of aspirin on colorectal cancer. Patients with PIK3CA mutation taking regular low-dose aspirin were found to have a significantly lower risk of colorectal cancer recurrence compared to those not taking aspirin. It is hypothesized that the inhibition of cyclooxygenase-2 (COX-2) through aspirin down regulates the PIK3CA signaling activity resulting in an inhibition of tumor cell proliferation. COX-2 is an important mediator of prostaglandin E2 (PGE2) production, which has been demonstrated to enhance tumor cell survival, angiogenesis and proliferation and reduce apoptosis. These extremely interesting and intriguing findings need to be confirmed in a prospective trial to potentially change clinical practice.

Objective(s)

The trial objective is to demonstrate a statistically significant and clinically relevant disease-free survival benefit in stage II and III PIK3CA mutated colon cancer patients taking daily adjuvant aspirin for 3 years.

Trial title

SAKK 41/13-Aspirin.
Adjuvant aspirin treatment
in PIK3CA mutated
colon cancer patients.

Clinical Phase

A randomized,
double-blinded,
placebo-controlled,
phase III trial.

Sponsor

Swiss Group for Clinical
Cancer Research (SAKK).

Coordinating investigator

U. Güller, CH-St.Gallen.

Colo-rectal cancer

OPERA: TRIAL OVERVIEW

- Patients entered into this study are those presenting with rectal cancer, located in the middle or lower rectum, and with an intermediate disease stage.
- This clinical study compares the efficacy of two techniques of radiotherapy, namely conventional, external (percutaneous) irradiation versus Contact X-Ray Brachytherapy, as local treatment of the disease.
- Its objective is to demonstrate that, after a first treatment with chemo- and radiotherapy, a complementary irradiation with Contact X-Ray Brachytherapy is superior to that with external radiotherapy, in terms of disease control and rectum (organ) preservation.
- Should this superiority be confirmed, the use of Contact X-Ray Brachytherapy could become standard treatment for patients with this type of rectal cancer and treated in centers equipped with such an irradiation device.

Study Title

European phase III study comparing, in association with neoadjuvant chemoradiotherapy, a radiation dose escalation using 2 different approaches: External Beam Radiation Therapy versus endocavitary Radiation Therapy with Contact X-Ray Brachytherapy 50 kV for patients with rectal adenocarcinoma cT2-T3 a,b < 5cm in diameter in distal and middle rectum.

Clinical Phase

Open-label, phase III, prospective, multi-centre, international, randomised 1:1, 2 arm study.

Sponsor

Centre Antoine Lacassagne (Cancer Research Center), F-Nice.

Coordinating investigator

J-P Gérard, F-Nice.

Patient population

Patients with rectal adenocarcinoma cT2-T3 a,b < 5cm in diameter in distal and middle rectum.

Background and Rationale

Rectal adenocarcinoma is rather radioresistant and the dose required to achieve 50% sterilization is close to 90Gy, which is a high dose causing toxicities when given with external beam radiation therapy (EBRT). Among the radiotherapy techniques able to achieve safely such a high dose, Contact X-Ray Brachytherapy 50 Kv (CXB) is an appealing method. There is a strong need to compare the two radiotherapy approaches in combination with neoadjuvant chemotherapy in patients with selected rectal cancers.

Objective(s)

To demonstrate that neoadjuvant chemoradiotherapy in combination with a boost given with Contact X-Ray Brachytherapy (Arm B) is superior to the same neoadjuvant therapy plus a boost with EBRT alone (Arm A) in terms of rectum (organ) preservation without non salvageable local disease at 3 years post treatment start, or permanent deviating stoma.

Pancreatic and gastric tumors

BAZEDOXIFENE: STUDY OVERVIEW

- Patients entered into this study are those presenting with advanced pancreatic and gastric tumors.
- Bazedoxifene, a selective estrogen receptor modulator clinically available for the treatment of osteoporosis, has shown to be an effective GP130/STAT3 signaling inhibitor through in vitro and small animal studies.
- The aim of the study is to investigate the effect of bazedoxifene on tumor progression in patients with advanced pancreatic and gastric tumors.

Patient population

The data of 7 patients (5 suffering from pancreatic and 2 from gastric adenocarcinoma), with locally advanced and/or metastatic disease, median age 73 years old (range 48 – 86 years) were analyzed. Bazedoxifene was given orally at a dose of 20 mg per day for a median duration of 9 months (range 5 – 14 months). Two patients received bazedoxifene as monotherapy, 5 patients were under concomitant chemotherapy.

Background and rationale

Experimental studies have shown that the IL6/GP130/STAT3 pathway is involved in pancreatic cancer tumorigenesis and progression as well as in the development of other tumors. Bazedoxifene, a selective estrogen receptor modulator clinically available for the treatment of osteoporosis, has shown to be an effective GP130/STAT3 signaling inhibitor through in vitro and small animal studies.

Objective(s)

The aim of the study is to investigate the effect of bazedoxifene on tumor progression in patients with advanced pancreatic and gastric tumors.

Outcome

Tumor marker reduction was found in 5 patients, stable disease on CT in 5 patients and metabolic regression on PET-CT in 3 patients. Weight was gained in 4 patients. 2 patients developed deep vein thrombosis and 1 pulmonary embolism, the treatment was otherwise well tolerated. An immuno-histochemical study of pSTAT3 was performed in 6 patients, out of which 3 were positive. Bazedoxifene is therefore a potential new therapeutic option for pancreatic and gastric cancer therapy, safe to use and at low cost. Based on these preliminary results, a prospective clinical study will be initiated.

Study Title

Bazedoxifene as a novel strategy for treatment of pancreatic and gastric adenocarcinoma.

Clinical Phase

Observational study.

Coordinating Investigator

Michel Forni, Centre d'Oncologie des Eaux-Vives, CH-Geneva.

All solid malignancies

NIVO-71: REGISTRY OVERVIEW

- Patients entered into this registry are those presenting with a metastatic solid tumor infiltrated by CD8+ T cells, which are cells of the immune system that contribute to the body's adaptive immune response.
- In this registry, patients are treated by immunotherapy, using nivolumab, an anti-PD-1 monoclonal antibody, working as a checkpoint inhibitor.
- The objective is to create a prospective registry of patients and define efficacy of nivolumab in patients with metastatic disease.

Project title

A registry for patients with progressing metastatic solid tumor infiltrated by CD8+ T cells and receiving nivolumab off-label in the Romand Network of Oncology (RRO).

Clinical phase

Prospective registry.

Sponsor

CHUV, CH-Lausanne.

Coordinating investigator

Olivier Michielin,
Department of Oncology,
CHUV, CH-Lausanne.

Patient population

Patients with progressing metastatic solid tumor infiltrated by CD8+ T cells and receiving nivolumab off-label in the Romand Network of Oncology (RRO)

Background and Rationale

Nivolumab is a fully humanized, monoclonal, immunoglobulin G4 (IgG4) antibody to PD-1. It is currently approved for locally advanced or metastatic non-small cell lung cancer (NSCLC), melanoma, clear cell carcinoma (CCR), squamous cell cancer of head and neck, and classical Hodgkin lymphoma.

Objective(s)

The primary objective is to create a prospective registry of patients with metastatic solid tumors infiltrated with CD8+ T cells for whom off-label nivolumab is prescribed.

The secondary objective is to define efficacy of off-label nivolumab and appropriateness of nivolumab indications.

The exploratory objectives are to perform translational studies on optional tumor biopsies and blood samples.

Impact of translational and outcome research programs on patient pathways: examples

TRANSLATIONAL RESEARCH

With the advent and improvement of new sequencing technology, next-generation sequencing (NGS) has been adopted in clinical oncology to advance personalized treatment of cancer. NGS is used to identify novel and rare cancer mutations, and provide molecular rationale for appropriate targeted therapy. Overall, continuous dedication to apply NGS in clinical oncology practice will enable us to be one step closer to personalized medicine. In this, the treatment of cancer patients progression, having previously received systemic drugs, can be guided by the use of NGS technology in selected cases among the population presenting with, among others, either lung, thyroid, ovarian, prostatic, breast cancer or melanoma. The biomolecular patterns identified in individuals by the Réseau Romand d'Oncologie can therefore determine, in selected patients, their therapeutic pathway instead of adhering to the "one-size-fits-all" policy. And this with higher probabilities of tumor response compared to conventional, not targeted approaches.

INTRA-OPERATIVE RADIOTHERAPY

Since 2009, the clinical research conducted at Clinique de Genolier for breast cancer patients allowed to modify the treatment pathway for those cases presenting with early or favorable disease (age above 50 years, ductal and other favorable histologies, unicentric and unifocal tumor with positive receptor status, pN0 (i-/i+), grade 1/2; tumor size < 2.5 cm; Luminal A). For this patient population, it was shown that intraoperative radiotherapy as sole treatment was a safe alternative approach, as compared to conventional external radiotherapy over 5-6 weeks. In addition, breast cancer patients presenting with intermediate risks can also benefit from the use of intra-operative radiotherapy, this time at a lower dose and in combination with external radiotherapy delivered over a shorter time of 2 weeks. In selected cases, intra-operative radiotherapy therefore improve the patient pathway during the postoperative phase.

OPHTHALMOLOGY

A prospective study conducted by Pr K. Mansouri, whose results were published in 2020, showed the feasibility of patient acquired measurement of intra-ocular pressure in conjunction with remote intra-ocular pressure monitoring by physicians with an implantable sensor. The data obtained had an impact on clinical decision-making, including adjustment of ocular hypotensive therapy and avoiding unnecessary office visits during the COVID-19 pandemic.



Education

In 2020, a range of medical conferences and seminars were organized (in most cases as virtual meetings, due to the restrictions imposed by the COVID-19 pandemic).

CLINIQUE GÉNÉRALE STE-ANNE, FRIBOURG

La hanche: du conflit à l'arthrose

Dr Xavier Le Duy	Public and medical conference	23.01.2020
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PRIVATKLINIK OBACH, SOLOTHURN

Update "Immunologie"	Medical conference	23.01.2020
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Update "Geriatric"	Medical conference	05.03.2020
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Update "Medizin"	Medical conference	25.06.2020
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Update "Schlaf und Müdigkeit"	Medical conference	24.09.2020
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Ärztetkollegium	Medical conference	12.11.2020
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CLINICA SANT'ANNA, SORENGO

Symposium perinatologie	Medical conference (online)	21.03.2020
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Radioprotection

Dr Paola Rodoni-Cassis	Formation	03.10.2020
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CLINIQUE DE GENOLIER, GENOLIER

COVID-19 et vaccins

Dr Philippe Glasson	Medical conference	25.06.2020
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SCHMERZKLINIK BASEL, BASEL

Lunch Lectures

Pr Kyburz (USB)	11.08.2020
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Dr Moser-Starck (USB)	01.09.2020
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Pr Valderrabano (SOC)	13.10.2020
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Dr Stöckl (Binningen)	10.11.2020
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Pr Daikeler (USB)	08.12.2020
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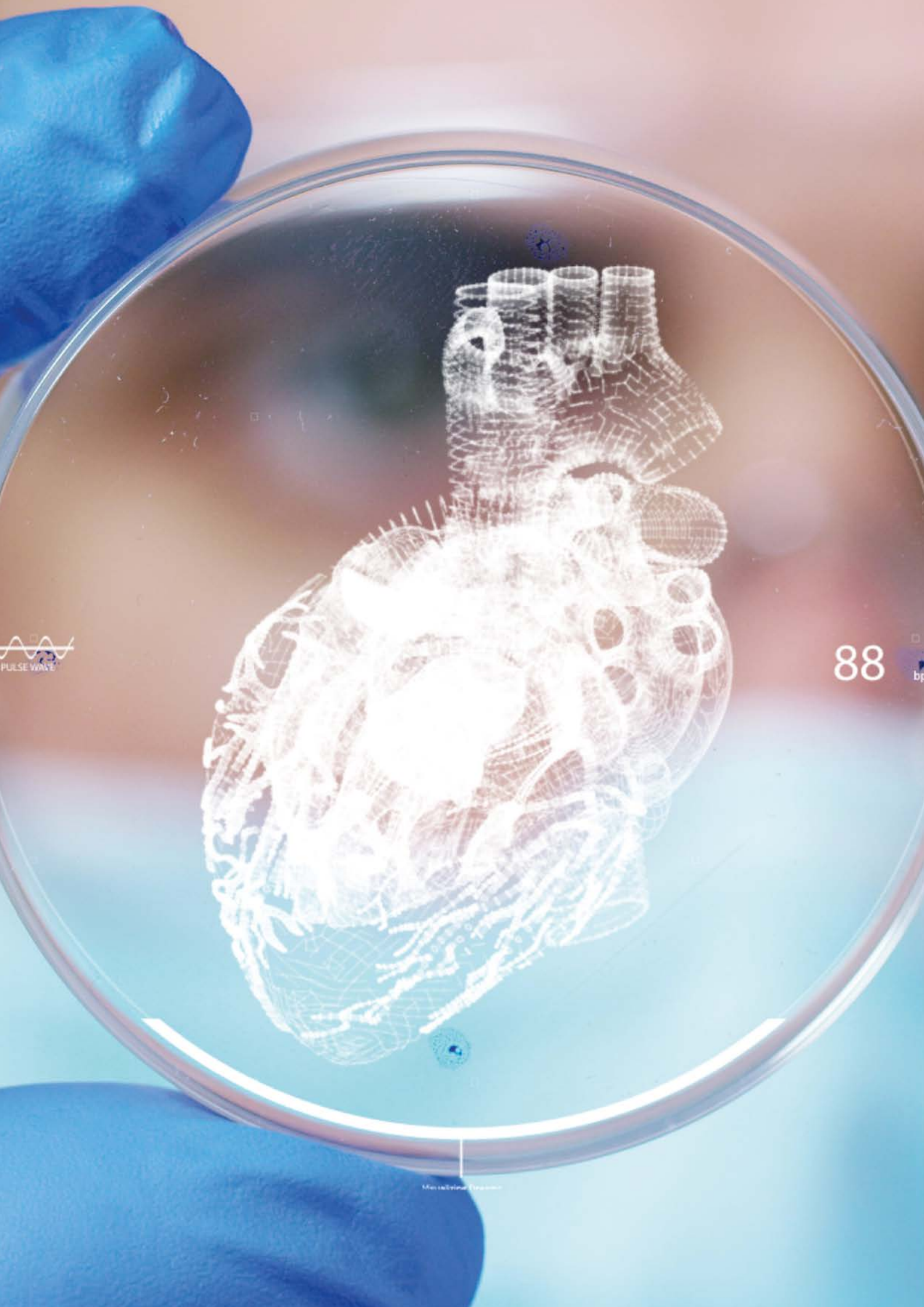
Conclusion

When Genolier Innovation Network was founded in 2019, the Network's medical teams and hospitals were lauded for their ability to conduct high-quality research programs. At the same time, it was obvious that the nascent stage of this scientific platform required significant efforts, at all levels, to both strengthen research structures and cement concerted scientific actions within Swiss Medical Network's sites.

The present report shows that, notwithstanding the deleterious impact of the COVID-19 pandemic on most healthcare ecosystems, the clinicians active within Swiss Medical Network's hospitals maintained high quantitative and qualitative levels of scientific activity. They defined clear research objectives, especially in value-based healthcare, and conducted through their participation to multi-center clinical trials focused scientific programs in a significant number of diagnostic and therapeutic domains.

In the clinical setting, these research programs pertain both to initiatives developed inside Genolier Innovation Network and ongoing collaborative projects with national and international cooperative groups as SAKK and EORTC. As regards translational research, it concentrates, for the time being, on the collaboration "Réseau Romand d'Oncologie" and Clinique de Genolier developed in the field of the bio-molecular approach to cancer treatment.

The remarkable quality levels already achieved by our medical teams will serve as a strong foundation for the Genolier Innovation Hub. Thanks to the integrated and interconnected activities between Genolier Innovation Network and Genolier Innovation Hub, this new research platform will facilitate cross-fertilization among all stakeholders and improve the chances of putting innovative solutions at the service of patients, scientists and physicians.





Scientific Publications in peer-reviewed journals (biomedical domains listed in alphabetical order)

Preamble: This list of bibliographical references is a compilation of scientific articles, physicians from Swiss Medical Network authored or co-authored in 2020, whose results were published by national/international cooperative groups or other institutions.

IMAGING

Interventional Radiology (P. Bize)

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