

2022 Annual Report Swiss GO Trial Group

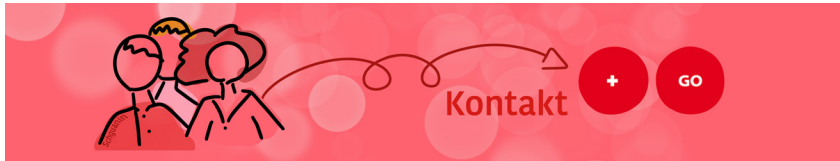


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The 2022 Annual Report is published on our website (www.swiss-go.ch).

To increase the readability of the text, only the masculine form is used in parts of this report, but it includes both the male and the female.



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Accounts for membership and donations

Membership

IBAN CH70 9844 0258 2736 6200 1 (Bank CLER)

Donations

IBAN CH43 9844 0258 2736 6200 2 (Bank CLER)

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Dear Colleagues, Members, Partners, and Supporters

An intriguing and eventful year 2022 lies behind us and a likewise interesting 2023 is waiting for us.

Swiss-GO is now in its fourth year after its foundation in 2019 and is continuously growing and becoming visible nationally as well as internationally.

I am very pleased to share with you some Swiss-GO highlights from 2022.

Swiss-GO has now 6 trials running: The MATAO trial (Swiss-GO-02) performs very well in Switzerland and Austria and now recruited more than 230 and enrolled more than 110 patients. A further boost in recruitment/enrollment is expected in 2023 after the opening of the German study sites. The IRMA trial (Swiss-GO-03) has reached 87% of its target recruitment. The Expression VI trial (Swiss-GO-01) has now completed recruitment, with Switzerland contributing 191 patients and making Switzerland the third-best recruiting country within this European trial. Its successor trials Expression IX (Swiss-GO-05) and XI (Swiss-GO-06) also recruit well in Switzerland. The BOUQUET trial (Swiss-GO-04) so far enrolled one patient in Switzerland (internationally: 75) and the MUSA (Swiss-GO-07) trial will start in early 2023. I am also very pleased to announce that the Swiss-wide OV Precision translational trial (Swiss-GO-08) and the international LoRiO trial (Swiss-GO-09) are expected to start in 2023/24, pending full funding.

Among the highlights were also the publication of the MATAO trial protocol in the peer-reviewed BMC Cancer journal (*McLaughlin PMJ et al., 2022*), the Annemarie Karrasch Forschungspreis 2022 awarded to Prof. Dr. med. Viola Heinzelmann-Schwarz for the MATAO trial, as well as the overwhelming resonance of this trial at international meetings and conferences. Within Swiss-GO, we have established the first of its kind centralized trial histopathology core facility within Switzerland to facilitate for the MATAO trial an international pathology reference center.

In recognition of Swiss-GO within the international study groups, the Gynecological Cancer Intergroup has accepted Swiss-GO as a trial group. Therefore, Swiss-GO is now a member of the European (ENGOT) and International Trial Group (GCI) Networks.

I am also very pleased that two more patients have agreed to join the «Patient Advocacy Group» within Swiss-GO, as they are essential of shaping of our trials, by participating and contributing in all of our trial meetings. This is increasingly becoming more important and valuable to design trials which truly benefit patients.

There are also challenges to be faced, such as the financing of the administration (with the continuously increasing workload for the Swiss-GO study management team) and the successful conduction of our clinical trials. We are therefore continuously trying to acquire support from third parties, as so far no institutional funding has been found for Swiss-GO.

Last but not least I, on behalf of the Swiss-GO Executive Board, would like to thank all participating patients, study nurses, local PIs, funding bodies and other supporters for the valuable contribution and participation in/for our studies, for the time invested to ensure the studies are conducted, and for the many helpful feedbacks, good ideas, and suggestions. I am especially grateful to the Swiss-GO management team, without its effort, commitment, and enthusiasm all our goals would be impossible to achieve. I am also grateful to Michael von Rotz, who joined the management team to assist Swiss-GO in financial matters, and Dr. Diego Calabrese and his team at the centralized histopathology review center. Likewise, the Executive Board members thank Dr. Maria Del Grande who resigned as Board member and welcomes Dr. Ilaria Colombo, IOSI Bellinzona, and Dr. Julian Zwimpfer, Inselspital Bern, as new Executive Board members.

We will continue to devote all our efforts to the well-being of patients suffering from gynecological cancer and hope for your support in this endeavor. The Swiss-GO Executive Board and myself look forward to your support, suggestions, discussions, exchanges, and to joint projects.



Prof. Viola Heinzelmann-Schwarz
President Swiss GO Trial Group

Basel, in May 2023



1. Activity of the Executive Board of Directors

The Board of Directors has in the fiscal year 2022 experienced a change in personnel. Dr. Maria Del Grande (Ente Ospedaliero Cantonale EOC, Bellinzona) resigned as Executive Board member as of October 2022 but remains a member of Swiss-GO. Instead Dr. Ilaria Colombo (IOSI, Bellinzona) signed in as new Executive Board member in October 2022.

In the 3 Board Meetings held in 2022, President Prof. Viola Heinzelmann-Schwarz presented to the board members the current status in regards to membership and financial matters, the progress in the ongoing trials, and the status quo in the planning of further trials. The financial matters and the budget were controlled and compiled by CFO Michael von Rotz and presented at the Executive Board Meetings by CEO PD Dr. André Fedier. The Financial Annual Statement was audited and approved by Dufour Treuhand AG Basel.

The Executive Board discussed and decided on concrete strategies and measures to increase the number of members, to improve membership fee payment practices, to raise financial resources through public and private sponsors, and to make Swiss-GO and its purpose and commitment more public and visible.



Foundation of Swiss GO Trial Group on 11. February 2019 in Basel.

Left to right: PD Dr. Marcus Vetter, Prof. Dr. Seraina Schmid, Prof. Viola Heinzelmann-Schwarz, PD Dr. Intidhar Labidi-Galy, lic.iur. Jacqueline Burckhardt, PD Dr. André Fedier.

2. Activity of the Office

The Swiss-GO Trial Group management team employs currently 5 project managers (PM), most of them working part-time for Swiss-GO and each of them assigned to specific trials. Dr. Pamela McLaughlin (PM for MATAO and responsible for the Swiss-GO website maintenance), Dr. Maren Vogel (PM for OV Precision and responsible for the Swiss-GO website maintenance), Claudine Bommer MA (PM for LoRiO), and Anett Jacob (PM for the Expression trials and responsible for accounting). Ms Feruza Ushurova, MTA, is responsible for the day-to-day work in the centralized histopathology unit and for communication with all study sites. Although they are assisted by study nurses and other personnel, the management team faces an inclining workload, owing the increasing number of ongoing studies and studies in the planning phase and not the least the complexity the study protocol conception and writing and establishment of the documentations for the various national and international authorities and legal bodies.

This has become accentuated while the COVID-19 pandemic, which forced the management team more or less from scratch to «go digital»: this included to establish remote (digital) patient QoL and vital sign assessment via an in-house newly designed digital QoL assessment questionnaire App and digital devices (wearables) and the remote training (via educational video clips) and assessment of external study sites.

An increase of the management team has become inevitable and search for funding sources is ongoing. Later in 2022, Michael von Rotz kindly agreed to assist regarding the Swiss-GO monetary controlling functioning as CFO.

The collaboration of Swiss-GO with the Clinical Trial Unit of the Department of Clinical Research (DKF) at the University Hospital Basel under the leadership of Prof. Christiane Magnus-Pauli is crucial. Her team of experts regarding trial design, statistical analysis, monitoring, and database implementation/follow-up and cleaning is essential for the success of our trial management.

Swiss-GO's interactive website is constantly updated and allows access for parts for interested patients and clinicians but also secure access for subcontractors and site investigators in regards to access to all trial protocols and contact details for patients and investigators available.

3. Activity of the Association

Swiss-GO actively and independently brings together interdisciplinary research and experts in the field of gynecologic oncology and, in particular, promotes the implementation of studies and research projects that develop new therapeutic and diagnostic approaches and aim at further research into the molecular causes of gynecological cancers. The focus lies on academic-driven, independent (not pharmaceutical industry-driven), and «out-of-the-box» investigator-initiated studies, the ideas for which not the least coming from research questions encountered in our own and in our colleagues' (translational) research laboratories. The intention is to increase the visibility of Switzerland's clinical research landscape, to foster the participation of Swiss sites in international trials and to improve Switzerland's recruitment rate within Europe. To achieve this Swiss-GO aims to play a pioneering role and hereby acts as main sponsor as well as supporter of such trials.

Six trials (Expression VI, IX, and XI; IRMA; MATAO; BOUQUET) are currently active under the Swiss-GO umbrella either as main sponsor or as collaborative supporter. While staying on track with the MATAO trial and even increasing the recruitment and enrollment rate in the last quarter due to the opening of the Austrian sites, one more trial (MUSA) is just ahead of starting and two others with Swiss-GO as main sponsor are expected to be launched in late 2023 (OV Precision, LoRiO).

The conduction of these trials would not be possible without the valuable contributions of all involved personnel. Swiss-GO slightly increased its number of members in 2022 and currently counts 41 contributing members and around 100 supporting trial management teams, clinicians, and health care staff in numerous national and European study sites.

Recognizing that public visibility and an active role in offering and conducting clinical trials, Swiss-GO is already widely networked with various groups and partner organizations, including ENGOT, GICG, SAKK, AGO Germany, AGO Austria, and Gynécologie Suisse and seeks further associations with other international study groups (more to be found on the website at www.swiss-go.ch) and is in early 2023 to appear on social media platforms like facebook and LinkedIn.

Since its launch in 2019 Swiss-GO made an impressive development and currently has 6 running trial in its portfolio, with at least 2 more trials being launched in the course of 2023 (Figure 1).

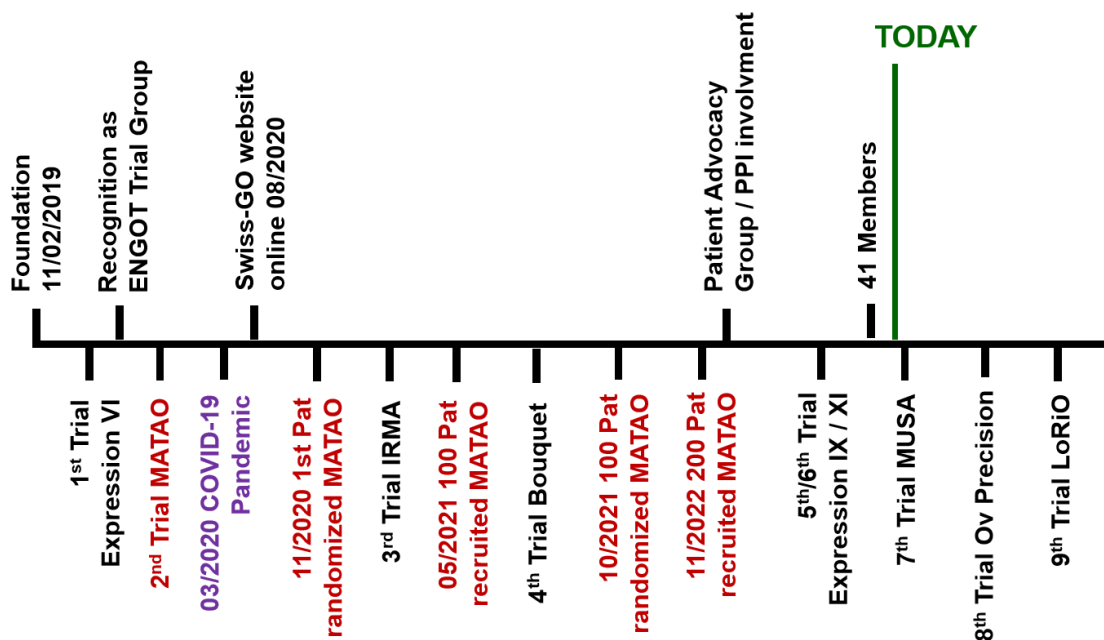


Figure 1. Development and trial portfolio of Swiss-GO (2019 – 2022).

3.1. Ongoing Clinical Trials



The **MATAO** trial (MAintenance Therapy with Aromatase inhibitor in epithelial Ovarian cancer; a randomized, double-blinded, placebo-controlled, multi-center phase III Trial, ENGOT-ov54/Swiss-GO-2; NCT04111978) is a maintenance therapy study with aromatase inhibitor (letrozole) for patients with epithelial ovarian cancer and is designed as a randomized double-blind placebo-controlled phase III study. This first international Swiss-GO-sponsored study is prospectively evaluating letrozole versus placebo for the first time as part of supportive therapy interventions in patients with serous and endometrioid ovarian cancer. The study is active since Fall 2020 with the inclusion of the first patients in Switzerland in November 2020.

Since then and despite the COVID-19 pandemic impact a total of 237 patients (+139 in 2022) were recruited and 115 (+68) enrolled into the study in the Swiss and Austrian centers (**Figure 2**). Also in 2022, the study received approval for conduct in 26 sites in Germany. This leaves us one and a half year to reach the enrollment target of 540 patients in these three countries.

Center	Center ID	Name of PI
Universitätsspital Basel	CH-01	Prof. Heinzelmann Viola
Kantonsspital Aarau	CH-02	Dr. Sarlos Dimitri
Kantonsspital Baden	CH-03	Prof. Heubner Martin
Kantonsspital Chur	CH-04	Dr. Schwitter Michael
Stadtspital Triemli	CH-05	Dr. Gabriel Natalie
Lindenhofgruppe Bern	CH-06	Prof. Rothmund Ralf
Kantonsspital Luzern	CH-07	Prof. Aebi Stefan
Onkozentrum Hirslanden Zürich	CH-08	Dr. Hirschi-Blickenstorfer Anita
Centre Hospitalier Universitaire Vaudois (CHUV)	CH-09	Dr. Sarivalasis Apostolos
Claraspital Basel	CH-10	Dr. Schmid Thomas
Kantonsspital St.Gallen	CH-11	Prof. Hornung René
Hôpitaux Universitaires de Genève (HUGE)	CH-12	PD Dr. Labidi-Galy Intidhar
Kantonsspital Thurgau-Frauenfeld	CH-13	Prof. Fehr Mathias
Spital Grabs SRRWS	CH-14	Prof. Schmid Seraina
Kantonsspital Winterthur	CH-15	Prof. Müller Andreas
Inselspital Bern	CH-16	Dr. Wampfler Julian
Kantonsspital Münsterlingen	CH-17	Dr. Taverna Christian
Universitätsspital Zürich	CH-18	Prof. Wicki Andreas
Kantonsspital Baselland Liestal	CH-19	PD Dr. Vetter Marcus
Hirslanden Klinik St. Anna Luzern	CH-20	Prof. Günthert Andreas
Instituto Oncologico Italiana Bellinzona (IOSI)	CH-21	Dr. Del Grande Maria
Medizinische Universität Innsbruck (MUI)	AT-01	Prof. Dr. Marth Christian
Klinik Hietzing (Hietzing)	AT-02	Dr. Denison Ursula
Krankenhaus Barmherzige Brüder Graz (BB Graz)	AT-04	Dr. Sevelda Ursula
Ordensklinikum Barmherzige Schwestern Linz (BHS Linz)	AT-05	Dr. Lafleur Judith

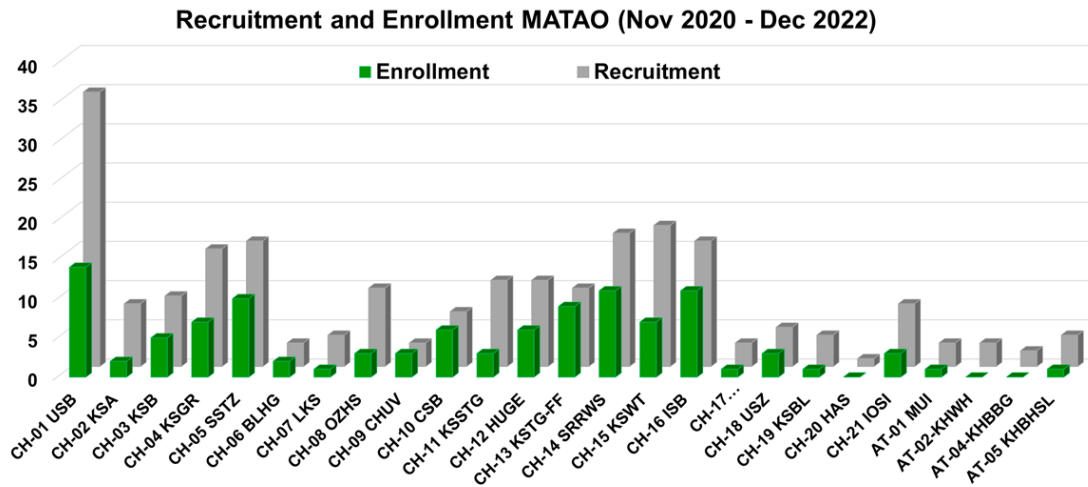
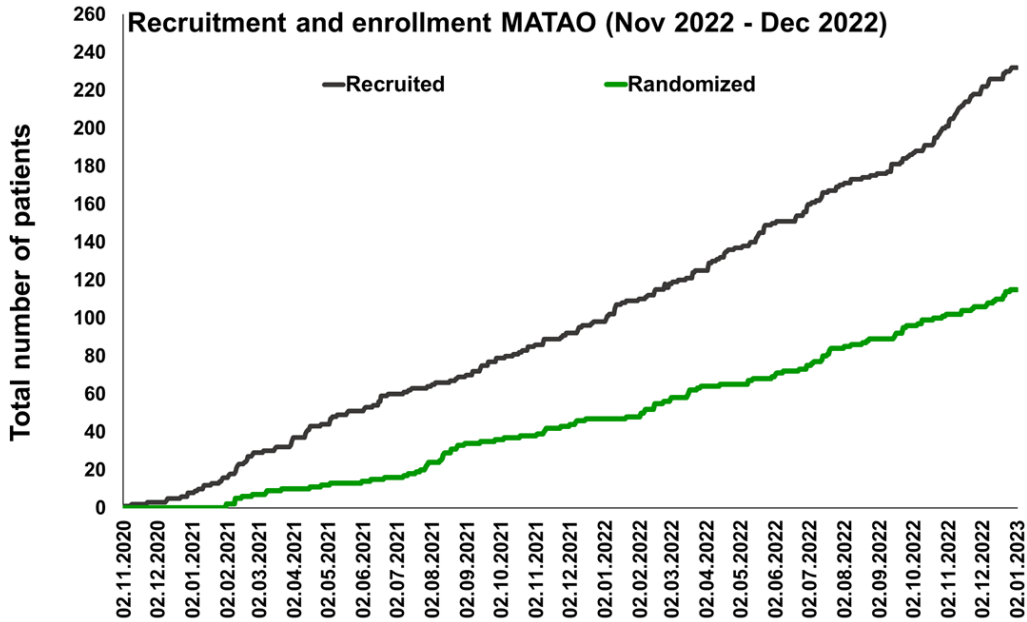


Figure 2.

Recruitment and randomization/enrollment rates as of end of 2022.

Top: Number of patients recruited and randomized into the MATAO trial since November 2020 and December 2022; Bottom: Currently recruiting centers in Switzerland (CH) and Austria (AT). Listing of Principal Investigators at the recruiting sites in Switzerland and Austria «is found on page 9.»

One milestone along with the MATAO study was the establishment of a centralized trial histopathology core facility (headed by Dr. Diego Calabrese, Department of Biomedicine of the University of Basel). The first of its kind in Switzerland, this core facility serves as the reference center for immunohistochemistry service for all MATAO trial sites, coordinates an international team of pathologists for the case review, organizes the logistics for sample transfer from the trial sites to the facility, provides a digital pathology and image analysis service for the sample analysis, and organizes a centralized MATAO biobank including tissue microarray production.

Since beginning, the facility has received more than 250 samples from the originating sites transferred to our infrastructure, performed more than 690 diagnostic assays and 225 image analyses and case reviews. An ad hoc interim analysis produced that primary diagnosis and estrogen-receptor status issued by the local pathology in the local centers in some cases diverge from that issued by the reference pathologists, providing a first indication upon the usefulness of a centralized pathology review facility (Figure 3).

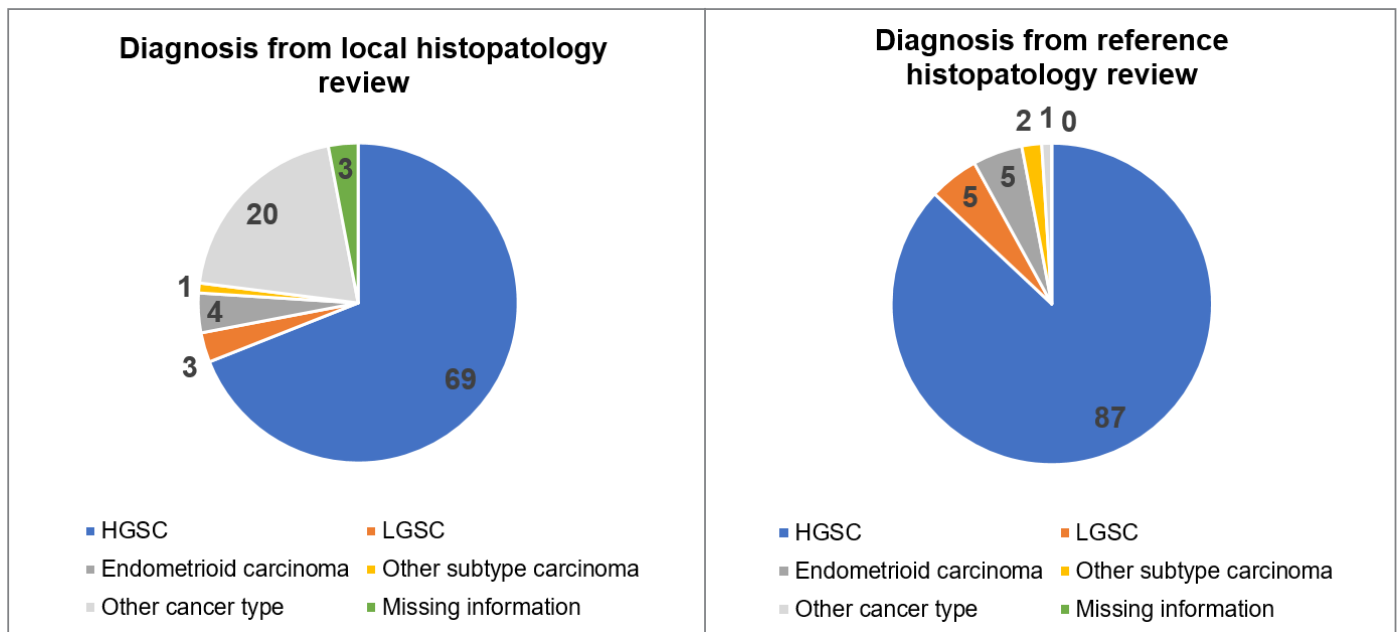


Figure 3. Divergence of primary diagnosis from the local pathology in the local centers (left) and the diagnosis from the reference pathologists (right). LGSC = Low-grade serous ovarian cancer; HGSC = high-grade serous ovarian cancer.

Another milestone, not the least owing the COVID-19 pandemic from 2020 to 2022, was to incorporate and implement digitalization into MATAO. Almost «from scratch» the study management team adapted the trial design, which included the remote (digital) QoL assessment by the patients via a newly designed digital QoL assessment questionnaire App, the remote vital sign assessment via digital devices (wearables), and the remote training (via educational video clips) and site assessment, not only replacing in-person on-site visits for study initiation, site staff training, and site monitoring, but also being cost saving.

The MATAO study was orally presented at the ENGOT Meeting (6.-7.10.2022) and the GCIG Autumn Meeting (25.-26.10.2022) in Berlin, and presented as poster at the DKF Tag der Klinischen Forschung at the University Hospital Basel (10.2.2022) and at the DGGG Annual Meeting (12.-15.10.2022) in München. The MATAO protocol was published in BMC Cancer, 2022;22(1):508 (<http://www.ncbi.nlm.nih.gov/pmc/articles/pmc9074273/>). Additional information on the trial can be found at: www.MATAO.ch.

MATAO is sponsored by Swiss-GO, with Prof. Viola Heinzelmann-Schwarz as International Project Lead, Sponsor Investigator, and Principal Investigator.

MATAO is a Model A ENGOT trial and is completely financed by third party money (approx. 2.5 Mio CHF): Supporters are Helsana Krankenkasse, AntiCancer Fund, Novartis Schweiz AG, Roche Pharma Schweiz AG, Krebsforschung Schweiz via the Mahari Stiftung, AGO Deutschland, AGO Österreich, and Stiftung Fürstlicher Kommerzienrat Liechtenstein.





The **Expression VI** study (Carolyn meets **HANNA**, **H**olistic **A**nalysis of lo**N**gterm survivors with ovaria**N** c**A**ncer/ENGOT-ov40/NOGGO S13/Swiss-GO-01) is an outcome research study. It facilitates questionnaires (digital or paper) to identify specific factors characteristic of this exceptional group of patients which are long-term ovarian cancer survivors beyond 5 years of diagnosis. This study, developed by the North-East German Society for Gynecological Oncology (NOGGO) and the European Competence Center for Ovarian Cancer of the Charité - Universitätsmedizin Berlin and supported by the German Foundation for Ovarian Cancer and the DIWA network, was global in scope within the international study groups GCIG and ENGOT and was active since November 2016 (recruitment now complete). The study results clearly indicate the need for specialized survivorship care after 5-year tumor-free survival.

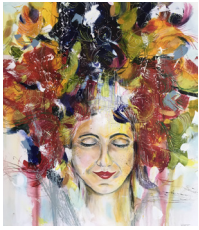
Switzerland's contribution to Expression VI is supported by funding of the Manja Gideon Stiftung (1'000 CHF) and coordinated by Swiss-GO and led by Swiss PIs Dr. Pierre Samartzis (University Hospital Zurich) and Dr. Tibor Zwimpfer (University Hospital Basel). In Switzerland, 191 patients (+13 in the reporting year 2022) have been enrolled, distributed across 12 centers, making Switzerland the third-best recruiting country within this European trial.



Motivated by the success of Expression VI, two successor Expression studies (IX and XI) were launched in Switzerland (Swiss PI Dr. Tibor Zwimpfer, financed and coordinated by Swiss-GO) and first questionnaire were dispatched to the patients in April 2022.



Expression IX study (Global **SURVEY** of LONG-TERM SURVIVAL with gynaecological **CANCER** (ENGOT-GYN4/NOGGO S20/Swiss-GO-05)) is an international multi center survey study for Long-term survivor patients (≥ 5 years) with the diagnosis of gynaecological cancer (cervical cancer, endometrial cancer, vulvar cancer, and rare gynaecological tumors such as sarcomas or granulosa cell tumor; excluding epithelial ovarian cancers). The current accrual status is 177 patients in 5 centers (end of 2022). Expression IX is sponsored by NOGGO ENGOT and Swiss-GO.



Expression XI study **IMPROVE** (International Survey for Patients with EndoMetrial Cancer: PeRspectiVes and Expectation of Therapy and Quality of Life. (ENGOT-en16/NOGGO S22/Swiss-GO-06)) is an international, multicenter center survey for patients with primary and relapsed endometrial cancer independent of their state of disease and treatment. The current accrual status is 265 patients in 9 centers (end of 2022: **Figure 4**). Expression XI is coordinated by NOGGO ENGOT and Swiss-GO.

Patients VI	Center	Patients IX	Center	Patients XI	Center
50	Universitätsspital Basel	98	Inselspital Bern	140	Inselspital Bern
34	Universitätsspital Zürich	67	Universitätsspital Basel	104	Universitätsspital Basel
20	Kantonsspital Aarau	11	Kantonsspital Baden	7	Stiftung Lindenhof Bern
15	Inselspital Bern	1	Other	5	Kantonsspital Baden
14	IOSI Bellinzona	0	Kantonsspital Luzern	4	IOSI Bellinzona
14	Stadtspital Triemli ZH	177	Total	3	Stadtspital Triemli ZH
10	Frauenfeld Kantonsspital			1	Claraspital Basel
8	Hôpital du Valais Sion			1	Kantonspital Münsterlingen
8	HUG Genève			0	Kantonspital Luzern
7	Chur Kantonsspital			265	Total
6	Kantonsspital Baden				
5	Schaffhausen KS				
191	Total				

Figure 4. Enrolled patients in the EXPRESSION studies in Switzerland (end of 2022).



The **BOUQUET** study (ENGOT-gyn2/GINECO/Swiss-GO-04/NCT04931342) is an international «open label» phase II study with 523 institutes and offers patients with rare gynecological tumors targeted treatment options tailored to their mutation status. Due to the rarity of these disease, the study was opened at only one site in Switzerland (Hôpitaux Universitaires de Genève HUG). It was initiated in June 2021. A total of 80-200 patients shall be enrolled in 2 phases: preliminary (n=20 per arm) followed by expansion (n=30 per arm), distributed across approximately 50-60 centers. Enrolled are patients with recurrent low-grade endometrioid, mucinous or clear cell ovarian cancer with up to 4 prior lines of chemotherapy), for whom platinum is no longer an option. Tumor specimen are sampled followed by NGS analysis. Depending on the mutations found, patients are distributed into 4 groups with, receiving a specified treatment (further details: www.swiss-go.ch). As of end of 2022, 61 centers are activated: 76 patients (out of 101 screened) have been enrolled (in Switzerland 1 enrolled out of 5 screened). The BOUQUET study is an international, pharmaceutical industry-sponsored (Hoffmann-La Roche, Genentech) ENGOT trial led by Prof. Isabelle Ray-Coquard, with PD Dr. Intidhar Labidi-Galy of HUG as representative for the Swiss site and Swiss-GO.



The **IRMA** study («Immediate breast **R**econstruction following **M**astectomy») (Swiss-GO-03) is a multicenter observational study of patients undergoing immediate breast reconstruction after prophylactic mastectomy or mastectomy due to breast cancer (NCT04390529). Objectives are to (i) prospectively record postoperative complications as well as tumor recurrence in these patients, (ii) record quality of life and cosmetic appearance, and (iii) make recommendations for an optimal approach to immediate breast

reconstruction based on the study results. A study protocol amendment was implemented to improve case report forms and patient-reported outcomes.

The IRMA study has currently 13 active study sites in Switzerland (**Figure 5**). In 2022, 103 patients were recruited, adding up to a total of 313 in-study patients since its launch mid 2017 (target recruitment number: 360). Interim results were presented at the 2022 Annual Meeting of the Swiss Society of Gynecology and Obstetrics and at the 2022 conference of the Swiss Society of Senology.

The IRMA study is led and sponsored by Prof. Mathias Fehr (Breast Center Thurgau), financed by Krebsliga Thurgau, and is also supported by Swiss-GO.



BrustCentrum Zürich, Bethanien & Zollikerberg
Brustzentrum Bern Biel, Hirslanden
Brustzentrum Thurgau
Hirslanden Clinique des Grangettes
Hôpitaux universitaires de Genève
Kantonsspital Aarau
Kantonsspital Baden
Lindenhofgruppe Bern
Ospedale Regionale Bellinzona e Valli / Lugano
Spital Wetzikon
Stadtspital Triemli
Tumor- und Brustzentrum Ostschweiz
Universitätsspital Zürich

Figure 5.
Recruiting IRMA centers.

3.2. Clinical Trials Starting in 2023

The **MUSA** trial (Ultrasound evaluation of the myometrium using the MUSA terminology, comparison with histology) is an observational (non)-interventional academic multicenter study that evaluates the diagnostic accuracy of the MUSA (**M**orphological **U**terus **S**onographic **A**ssessment) terms and definitions to differentiate between different types of myometrial lesions of more than 1cm. MUSA terms, definitions, and measurements describe the sonographic features of myometrium and uterine masses and have been published as a consensus paper in 2015 (Van den Bosch et al, Ultrasound Obstet Gynecol;46:284-98). The aim is to apply this new terminology in daily gynecological ultrasound practice and to evaluate prospectively if the ultrasound appearance of the myometrium, as described by the MUSA terminology, can predict myometrial pathologies.

The MUSA trial is sponsored by University Hospitals Leuven (Prof. D. Dirk Timmerman), with PD Dr. Gwendolin Manegold-Brauer (University Hospital Basel) as responsible collaborator and representative for Swiss-GO. Ethical Committee approval was granted in November 2022 and start is planned for early 2023.



The **OV Precision** study (Cancer-Profiling-based Precision Treatment in Ovarian Cancer, a prospectively randomized-controlled Swiss Trial) is the continuation of the TuPro Trial on an advanced level. TuPro provided the basis with valuable information about tumor biology, imitable for each individual and specimen, providing treatment prognostications to select the best therapy option for the patient. OV Precision is a multicenter randomized, controlled open trial comparing serous ovarian cancer to experimental treatment based on in-depth molecular analysis by the approved and validated cancer-profiling technology platform.

The OV Precision trial aims to prove the hypothesis that (A) the TP enables oncologists to choose the best possible therapy for the individual patient resulting in a better outcome and (B) the TP test will allow therapy adaptation (i.e. potential downscaling), subsequently leading to reduced side effects and a better quality of life for the patient. Results from this trial will be a landmark for other diseases in similar settings and will make the path towards truly personalized treatment in oncology. Target group of patients in this trial are the ones with the worst prognosis and in the highest area of need in regard to improved treatment strategies: patients with tumors proficient (functional) in homology-directed repair (HRP).

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OV Precision is a Swiss trial with 10 sites, mostly the top-recruiting in ENGOT-ov54/Swiss-GO-02/ MATAO trial with confirmed interest and robust accrual estimates. OV Precision study is partially financed by third-parties (among others: Lotte und Adolf Hotz-Sprenger Stiftung, Baugarten Stiftung, Swiss National Science and Technology Forum (SNSTF), Ursula Ströher Stiftung, Ulrich und Klara Huber-Reber-Stiftung), with PI Prof. Viola Heinzelmänn-Schwarz and sponsored by Swiss-GO. Planned start is in Fall 2023.



URSULA STRÖHER STIFTUNG

3.3. Planned Clinical Trials in 2024

The **LoRiO** (Localized Radiotherapy with concurrent Olaparib in platinum-sensitive recurrent Ovarian cancer vs. standard of care: a randomized multicenter phase II trial) is a 1:2 randomized, controlled, international (within ENGOT), multicenter phase II study of approximately 160 patients with recurrent (first or second line of relapse) platinum-sensitive epithelial ovarian carcinoma (including fallopian tube and peritoneal cancer) after secondary debulking.

The aim of the trial is to prove and evaluate that localized radiotherapy in combination with PARPi in patients with recurrent, platinum-sensitive ovarian cancer improves disease control while avoiding chemotherapy and reducing the associated side effects. The primary objective is to determine if PARPi and radiotherapy are better in terms of progression-free survival than the standard treatment chemotherapy. Importantly, the study will also evaluate the overall survival of patients and patient-reported outcomes through Quality-of-Life questionnaires.

LoRiO is planned to start early 2024 with recruitment and treatment, followed by a maintenance and follow-up period of 4 years.

Swiss-GO is the sponsor, with Prof. Viola Heinzlmann-Schwarz as Principal Investigator. Expected costs of the study are approx. 2.6 Mio CHF, whereof 1/3 are assured by other study groups (CEEGOG, ISGO). Remaining funding for LoRiO is pending.



3.4. Swiss-GO Patient Advisory Board

The «Patient Advocacy Group» was founded and integrated into the Swiss GO Trial Group late 2021. **Figure 6** shows Yolanda Hofer, Mubera Krijezi, and Dr. Katrin Stamm who have agreed to serve as Patient Advocacy Board for Swiss-GO studies. We are happy to welcoming two new members, Michelle Cullom and Doreen Parrish (not in figure) to the Patient Advocacy Group.

The integration of the «Patient Advocacy Group» met a need. It is increasingly recognized that the involvement of patients, caregivers, patient advocates, patient experts and patient organizations in research and development offer benefits for all involved parties. The involvement of the patients assures the efficient co-working of clinical and medical research and hence delivers what most matters to the patients, improves the quality, and may prevent potential challenges that patients may face during the conduct of a study It also strengthens the public credibility of the evidence generated, enables more effective dissemination of research results outside of scientific target groups, and strengthens uptake and use of research outcomes in clinical practice. Within this, patients may take various roles: they provide feedback information design, serve as advisory committee members or provide advice prior to a study on outcomes of importance and study design.



Figure 6.
Foundation of the Swiss-GO Patient Advisory Board in 2021.
From left to right: Prof. Viola Heinzelmann-Schwarz, Yolanda Hofer, Dr. Katrin Stamm, and Mubera Krijezi.

3.5. Events, Meetings, Congresses, Publications, Awards

Swiss-GO and Swiss-GO associated Meetings

MATAO CH-D-A Investigator Meeting, (5.-6.3 2022, virtual)
Swiss-GO Board Meeting (20.6.2022, Basel, virtual)
Swiss-GO General Assembly (20.6.2022 Basel, virtual)
Swiss-GO Board Meeting (3.10.2022, Basel, virtual)
Swiss-GO Board Meeting (12.12.2022, Basel, virtual)
Swiss-GO Weekly Staff-Meeting (Mondays, in person)

Other Meetings with attendance of Swiss-GO

SAKK In-between Meeting I: 10.3.2022 (virtual)
SAKK Semi-Annual Meeting: 5.-6.5.2022 (Zurich)
SAKK In-between Meeting II: 22.9.2022 (virtual)
SAKK Semi-Annual Meeting II: 16.11.2022 (Basel)

Congress contributions

MATAO-Study

ENGOT Assembly Meeting (6.-7.10. 2022, Berlin, D)
GCIG Autumn meeting (25.-26.10. 2022, Berlin, D)
DKF Tag der Klinischen Forschung, Universitätsspital Basel (10.2.2022, Basel, CH)
DGGG, 64. Jahreskongress (12.-15.10.2022, München, D)

IRMA-Study

Swiss Society of Gynecology and Obstetrics (SGGG) Annual Meeting 2022 (St.Gallen, CH): Poster presentation (Dr. Lipp von Wattenwyl, Breast Center Svizzera Italiana).

Swiss Society of Senology (SSS) Conference 2022 (Innsbruck, AT): Poster presentation (Dr. Wieland Sell, Spital Thurgau AG).

Publications

Maintenance Therapy with Aromatase Inhibitor in epithelial Ovarian Cancer (MATAO): study protocol of a randomized double-blinded placebo-controlled multi-center phase III Trial.

McLaughlin PMJ, Klar M, Zwimpfer TA, Dutilh G, Vetter M, Marth C, du Bois A, Schade-Brittinger C, Reuss A, Bommer C, Kurzeder C, Heinzelmann-Schwarz V. BMC Cancer. 2022;22:508. doi: 10.1186/s12885-022-09555-8. PMID: 35524184.

Clinical research in ovarian cancer: consensus recommendations from the Gynecologic Cancer InterGroup.

Vergote I, Gonzalez-Martin A, Lorusso D, Gourley C, Mirza MR, Kurtz JE, Okamoto A, Moore K, Kridelka F, McNeish I, Reuss A, Votan B, du Bois A, Mahner S, Ray-Coquard I, Kohn EC, Berek JS, Tan DSP, Colombo N, Zang R, Concin N, O'Donnell D, Rauh-Hain A, Herrington CS, Marth C, Poveda A, Fujiwara K, Stuart GCE, Oza AM, Bookman MA; participants of the 6th Gynecologic Cancer InterGroup (GCIg) Ovarian Cancer Consensus Conference on Clinical Research. Lancet Oncol. 2022:e374-e384. doi: 10.1016/S1470-2045(22)00139-5.

PRIMA/ENGOT-OV26/GOG-3012 Investigators. Impact of disease progression on health-related quality of life of advanced ovarian cancer patients. Pooled analysis from the PRIMA trial.

Chase DM, Marín MR, Backes F, Han S, Graybill W, Mirza MR, Pothuri B, Mangili G, O'Malley DM, Berton D, Willmott L, Baumann K, Coleman RL, Safra T, Heinzelmann-Schwarz V, Lorusso D, Karl FM, Woodward T, Monk BJ, Gonzalez-Martin A; Gynecol Oncol. 2022:S0090-8258(22)00432-2.

Award

Annemarie Karrasch Forschungspreis 2022 (25'000 CHF) to Prof. Dr. med. Viola Heinzelmann-Schwarz for the MATAO trial.

3.6. Public Relations

The interactive website «Swiss GO Trail Group» (www.swiss-go.ch) and the printed brochure (2022 Annual Report) provide an overview of the various activity of Swiss-GO, information on ongoing and planned clinical trials, on academic and health-related events, partner organizations, and about selected gynecological diseases. It also offers a detailed information package for researchers, patients, interested parties. Swiss-GO from now on will also be public on social media (Facebook, LinkedIn).

4. Finances and Budget

Swiss-GO's ongoing operating budget (accounting, auditing, costs for printed matter and mailings, banking fees) is covered by contributions of its members, while the costs for the administration (e.g. study management, documentations for legal authorities) and the conduction of the clinical trials themselves ideally are covered by third parties (private foundations and associations, academic and health-related institutions, and health care companies). Currently, the MATAO trial (2.5 Mio CHF) and the OV Precision trial (2.4 Mio CHF) are financed through third parties.

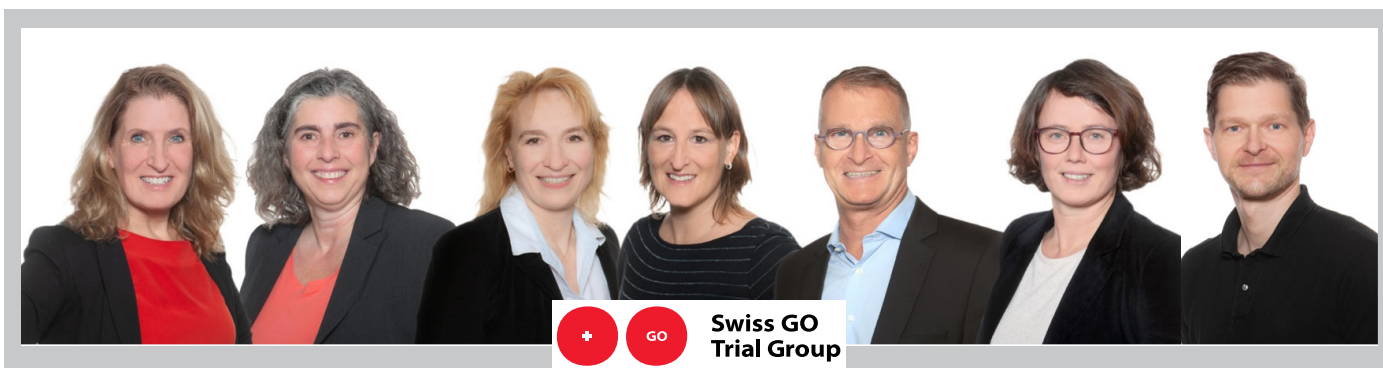
However, as non-profit association and to make the successful conduction of our clinical studies possible Swiss-GO depends on financial contributions not only from the above-mentioned funding bodies but also from private persons and undertakes all its efforts towards this aim.

Swiss-GO's fortune per 31.12.2022 amounts to CHF 26'814 (+1'826 in 2022). An income of CHF 5'947 (5'650 from membership fees and 297 from a donation) matches expenses of CHF 2'940 (2'850 from accounting and auditing by Dufour Treuhand AG and 98 from banking fees).

A detailed summary of the 2022 Financial Annual Statement audited and approved by Dufour Treuhand AG Basel can be found on the Swiss-GO website (www.swiss-go.ch) «Jahresrechnung Geschäftsjahr 2022».

5. Appreciation

We are very grateful to all our partners, collaborators, supporters, and the staff at each study center for their enthusiasm and commitment, generous support, and enormous effort in 2022 for Swiss-GO.



Swiss-GO Management Team 2022

Dr. Pamela McLaughlin, PhD (Clinical Scientist/Clinical Trial Manager), Dr. Maren Vogel, PhD (Scientist/Clinical Trial Manager), Prof. Dr. med. Viola Heinzlmann (President of Swiss-GO), Claudine Bommer, MSc (Clinical Trial Manager), PD Dr. André Fedier, PhD (CEO Swiss-GO), Anett Jacob (Clinical Trial Manager), Michael von Rotz (CFO Swiss-GO).



Jahresrechnung

Swiss GO Trial Group

Geschäftsjahr 2022

Enthaltend:

- Bilanz
- Erfolgsrechnung
- Anhang

Gewinnverwendungsvorschlag

4031 Basel

Bilanz per 31.12.2022

Aktiven	31.12.2022	31.12.2021
	CHF	CHF
Bankguthaben	26'813.97	23'612.77
Flüssige Mittel	26'813.97	23'612.77
Forderungen gegenüber Dritten	600.00	2'750.00
Wertberichtigung	600.00	1'375.00
Forderungen aus Lieferungen und Leistungen	0.00	1'375.00
Umlaufvermögen	26'813.97	24'987.77
Total Aktiven	26'813.97	24'987.77

Bilanz per 31.12.2022

Passiven	31.12.2022	31.12.2021
	CHF	CHF
Passive Rechnungsabgrenzungen	2'800.00	2'800.00
Kurzfristiges Fremdkapital	2'800.00	2'800.00
Fremdkapital	2'800.00	2'800.00
Vereinskapital	22'187.77	21'570.77
Jahresgewinn / -Jahresverlust	1'826.20	617.00
Bilanzgewinn / -Bilanzverlust	1'826.20	617.00
Eigenkapital	24'013.97	22'187.77
Total Passiven	26'813.97	24'987.77

Erfolgsrechnung 01.01.2022 - 31.12.2022

Erfolgsrechnung	2022	2021
	CHF	CHF
Dienstleistungserlös	5'372.30	4'900.00
Erlösminderungen	-600.00	-1'375.00
Nettoerlös aus Lieferungen und Leistungen	4'772.30	3'525.00
Bruttogewinn	4'772.30	3'525.00
Verwaltungs- und Informatikaufwand	2'850.45	2'833.40
Übriger betrieblicher Aufwand	2'850.45	2'833.40
Betriebserfolg vor Finanzerfolg, Steuern und Abschreibungen (EBITDA)	1'921.85	691.60
Betriebserfolg vor Finanzerfolg und Steuern (EBIT)	1'921.85	691.60
Finanzaufwand	97.90	76.80
Finanzertrag	2.25	2.20
Finanzerfolg	-95.65	-74.60
Betriebserfolg vor Steuern	1'826.20	617.00
Jahresgewinn / -Jahresverlust vor Steuern	1'826.20	617.00
Jahresgewinn / -Jahresverlust	1'826.20	617.00

Anhang zur Jahresrechnung

Anhang

31.12.2022

31.12.2021

Angewandte Grundsätze

Die vorliegende Jahresrechnung wurde gemäss den Vorschriften des Schweizer Gesetzes, insbesondere der Artikel über die kaufmännische Buchführung und Rechnungslegung des Obligationenrechts (Art. 957 bis 962) erstellt.

Die Rechnungslegung erfordert von der Geschäftsführung Schätzungen und Beurteilungen, welche die Höhe der ausgewiesenen Vermögenswerte und Verbindlichkeiten sowie Eventualverbindlichkeiten im Zeitpunkt der Bilanzierung, aber auch Aufwendungen und Erträge der Berichtsperiode beeinflussen könnten. Die Geschäftsführung entscheidet dabei jeweils im eigenen Ermessen über die Ausnutzung der bestehenden gesetzlichen Bewertungs- und Bilanzierungsspielräume. Zum Wohle des Vereins können dabei im Rahmen des Vorsichtsprinzips Abschreibungen, Wertberichtigungen und Rückstellungen über das betriebswirtschaftlich benötigte Ausmass hinaus gebildet werden.

Vollzeitstellen im Jahresdurchschnitt

Anzahl Vollzeitstellen im Jahresdurchschnitt

keine

keine

Sonstige Angaben

Steuerbefreiung und Spendenabzug:

Gemäss Schreiben der Steuerverwaltung Basel-Stadt vom 11. Juni 2019 erfüllt der Verein Swiss Go Trial Group alle Voraussetzungen. Die Steuerbefreiung wurde sowohl für die kantonalen Steuern wie auch für die direkte Bundessteuer anerkannt. (Die Steuerbefreiung erstreckt sich allerdings nicht auf die Grundstückgewinnsteuer und nur dann auf die Grundsteuer, wenn eine gehaltene Liegenschaft nicht vermietet sondern unmittelbar dem gemeinnützigen oder öffentlichen Zweck entsprechend genutzt wird.)

Im weiteren hat die Steuerverwaltung mitgeteilt, dass Zuwendungen an den Verein von im Minimum CHF 100.-- im Jahr bei den direkten Steuern gemäss den gesetzlichen Bestimmungen (§ 33 lit. b und § 70 lit. c StG resp. Art. 33 a DBG und Art. 59 Bst. c DBG) abziehbar sind. Die Abzugsfähigkeit ist nach oben auf 20 % der um die Aufwendungen gemäss §§ 27 - 32 StG und Art. 26 - 33 DBG verminderten steuerbaren Einkünfte resp. auf 20 % des steuerbaren Reingewinns begrenzt.

Anzahl Mitglieder am Ende des Geschäftsjahres (inkl. Vorstandsmitglieder):

41

37

Antrag des Vorstandes über die Gewinnverwendung

Gewinnverwendung	31.12.2022	31.12.2021
	CHF	CHF
Vortrag aus dem Vorjahr	22'187.77	21'570.77
Ertrags- (+) / Aufwandsüberschuss (-)	1'826.20	617.00
Total Bilanzgewinn	24'013.97	22'187.77
Vortrag auf neue Rechnung	24'013.97	22'187.77
Total Bilanzgewinn	24'013.97	22'187.77

Contact information
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