



Annual Report 2024

Stichting EUOG

Management Report

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Management Report

Management Report 2024 of the Board of the EUOG

General

The Board has met twice in 2024 on June 28 and on December 22 by videoconference. Present: Mr. I.J. de Jong, Mr. W. Loidl, Mr. H. van Poppel, Mrs. S. Osanto.

Information about EUOG's mission in 2024 and beyond and strategy and -in accordance with requirements for the ANBI status (non-profit, charity foundation)- the Annual Report can be found on the website www.euog.org. The financial statements have been prepared by Bunnig & Partners Accountants in Leiden in cooperation with the EUOG Foundation.

Clinical Research

1. Prostate Cancer

Of the 2 EUOG studies in investigating the clinical utility of WB MRI and PET CT scan in patients with hormone-sensitive metastatic prostate cancer ("HORNA study") or chemotherapy-naïve metastatic castration-resistant prostate cancer ("CHENA study") undergoing enzalutamide treatment there is still a considerable proportion of patients in HORNA who is in clinical remission receiving enzalutamide treatment in 2024. Enzalutamide has been supplied still in 2024 to hormone-sensitive metastatic prostate cancer patients experiencing clinical benefit from enzalutamide treatment. Long-term follow up will be reported in 2025.

2. E-health in prostate cancer

Results of a systematic review of health-related quality of life (HRQoL) from pivotal phase 3 randomized controlled trial (RCTs) in patients with metastatic hormone-sensitive prostate cancer has been reported in Lancet 2024. The SR showed heterogeneity between the various large randomized trials and low risk of bias.

3. Upper Tract Urinary Cancer

URANUS trial

Efforts were made to increase the inclusion rate of the URANUS trial in upper urinary tract urothelial cell carcinoma (UTUC). Uranus is a difficult trial to run for various reasons including the rarity of the tumour in a population of elderly patients with co-morbidities. Also, the outcome of the POUT trial showing an improvement of disease-free survival (DFS) but not overall survival by adjuvant chemotherapy which has affected standard of care in some centers and countries.

In 2024, it was decided to establish a larger network of participating centers to form a global consortium that addresses this rare disease. Three new Research Groups were approached and invited to join the URANUS Trial, the new Guard Consortium (Genito-Urinary Alliance for Research and Development), the Latin American Renal Cancer Group (LARCG) and Taiwan Upper Tract Urothelial Carcinoma Collaborative Group. These efforts resulted in a total of 27 new centers in 5 countries (Argentina, Brazil, Colombia, Uruguay, Taiwan) which are now associated with the URANUS trial. Ethic Committee approval has been obtained for the majority of these centers and these enters are expected to be activated by 2nd or 3rd quarter of 2025.

Logistics of new European Medicines Agency requirement for ongoing trial in Europe

Logistics around any trial active beyond end of January 2025 in Europe in the sense of the obligation to migrate from EUDRACT to the European Medicines Agency (EMA) driven new Clinical Trials Information System (CTIS) had to be dealt with.

Simultaneously a new version of the protocol (amendment, Version 5.0 dd. July 4, 2024) was prepared to change inclusion criteria in the URANUS trial to align with kidney function cut offs used in POUT and other trials in UTUC and to allow carboplatin-based chemotherapy in the adjuvant setting.

EUOG was obliged to first prepare the transition to the new EMA CTIS for the old version of the URANUS protocol. After submission this was approved in November 2024.

Thereafter EUOG was allowed to introduce the already prepared amended protocol for Europe, i.e. EU 5.0 dd. July 4, 2024, in the CTIS system. Both procedures were required to perform sequentially and this took a lot of effort and time. The new CTIS system was not user-friendly and had major administrative challenges, while EUOG had to deal with different procedures and parties within each participating country. The new strict CTIS procedures thus caused a considerable delay, also as new centers in Spain had to wait to be introduced in the 2nd wave of the version 5.0 protocol being introduced in CTIS.

In addition, based on the changes in the design of the trial in the new protocol version the digital Case Report Forms (CRF) designed by ALEA needed to be modified and introduced into the digital ALEA system.

Monitoring participating centers

In line with the URANUS Monitoring Plan, recruiting centers in Spain and the Netherlands were visited to monitor. Monitoring visits were also performed in Norway.

Investigator meeting

EUOG organized one investigator meeting during 39th Annual European Association of Urology Congress (EAU) in April 2024 in Paris with the participation of members of the Taiwanese Upper Tract Urothelial Carcinoma Collaboration Group.

Financial report

The expenses of the EUOG Foundation were for daily operational costs, salaries, insurances and accountant expenses. Furthermore, the foundation has reimbursed participating hospitals in studies to compensate expenses. The balance on the bank accounts was on December 31, 2024 €.

1.719,460

Conclusion

The Foundation will continue to contribute to cancer research through Europe and beyond, with the aim to find new and better solutions for cancer patients. To make this possible and to continue these activities, the Foundation is striving to obtain grants, donations and gifts.

Leiden, June 29, 2025 signed

Chairman, S. Osanto (on behalf of the entire board)

Secretary-Treasurer, I.J. de Jong (agreed during the board meeting)

Board member, W. Loidl (agreed during the board meeting)

Board member, H. van Poppel (agreed during the board meeting)

Financial statements

Stichting EUOG

Balance sheet

After appropriation of the result.

Balance sheet assets

	31-12-2024	31-12-2023
Fixed assets		
Tangible fixed assets	1,106	1,965
Financial fixed assets	1,695,470	1,671,178
	1,696,576	1,673,143
Current assets		
Cash and cash equivalents	22,885	46,487
	22,885	46,487
Assets	1,719,460	1,719,630

Balance sheet equity and liabilities

	31-12-2024	31-12-2023
Equity		
Special-purpose reserves	<u>1,699,010</u>	<u>1,684,203</u>
	1,699,010	1,684,203
Current liabilities	20,450	35,428
Equity and liabilities	<u>1,719,460</u>	<u>1,719,630</u>

Statement of income and expenses

Statement of income and expenses

	Reporting year		Last year
	2024		2023
Purchase value of income	8,885	12,744	
Balance	-8,885		-12,744
Employee expenses	89,581	86,647	
Depreciation	859	859	
Housing expenses	0	7,449	
Inventory expenses	0	35	
Sales expenses	3,394	2,973	
Office expenses	745	0	
General expenses	10,107	9,067	
Total expenses	104,686		107,030
Balance income and expenses	-113,572		-119,774
Financial income and expenses	128,379		125,369
Result	14,807		5,595

Result appropriation

	Reporting year		Last year
	2024		2023
Result appropriation			
Special-purpose reserve	14,807	5,595	
	14,807		5,595