

21 22 M A Y 23 24 2025 ATHENS, GREECE

VENUE ROYAL OLYMPIC HOTEL

PROGRAM

SECRETARIAT

INTERNATIONAL PROGRAM APPROVAL

SCIENTIFIC AND EDUCATIONAL CONTENT ENDORSED BY

UNDER THE AUSPICES



CONCO MEETINGS & EVENTS
35, Sorou Str. | GR 151 25,
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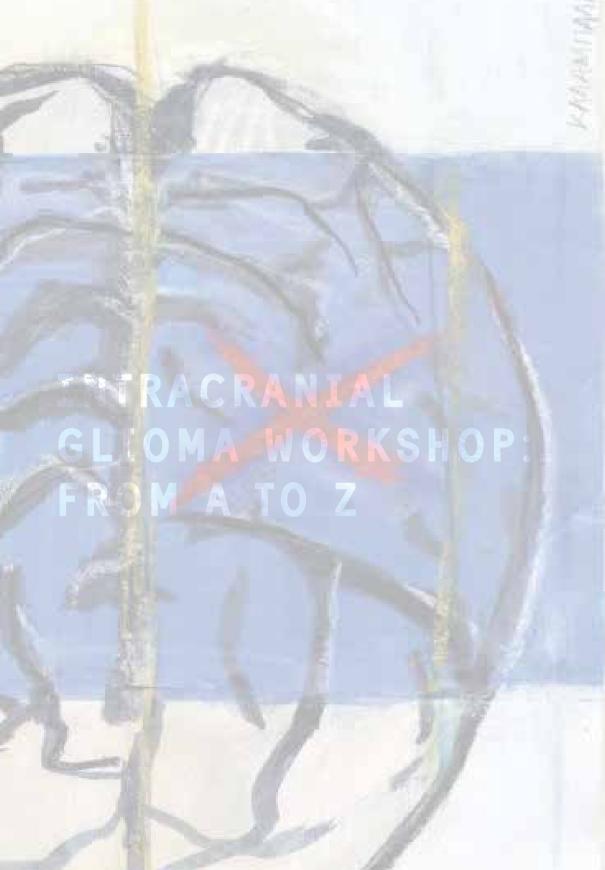




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ORGANIZER



Department of Neurosurgery School of Health Sciences University of Thessaly

COURSE SECRETARIAT



CONCO Meetings & Events a/35, Sorou Str., 15125, Athens, Greece t/+30 210 6109991 w/www.concopco.com @/dnikolopoulou@concopco.com

WELCOME ADDRESS

Dear Colleagues,

It is our great pleasure to welcome you to our comprehensive practical workshop of diagnosing and managing patients with intracranial gliomas. Our course is aiming at covering all aspects of gliomas, from their genetic analysis and profiling to the most advanced surgical resective techniques and the long-term follow-up and support of these patients. An astonishing multi-national faculty, including leading figures in the field of neuro-oncology constitutes a guarantee that the participants will be able to familiarize themselves with all advanced imaging and surgical techniques, utilized for the most efficient and the safest management of patients with intracranial gliomas. A well-balanced combination of vivid presentations, stimulating debates, highly-didactic video sessions, and practical hands-on will ensure that each participant will be exposed to all diagnostic methodologies, to the most updated surgical strategies and to the most recent adjuvant treatment protocols.

The event is hosted in Athens, at the Royal Olympic Hotel, situated in the heart of the city center and easily accessible via public transportation, that connects it with the rest of the city.

We welcome you all and we are looking forward to making this an unforgettable experience for you.

With our warmest regards,

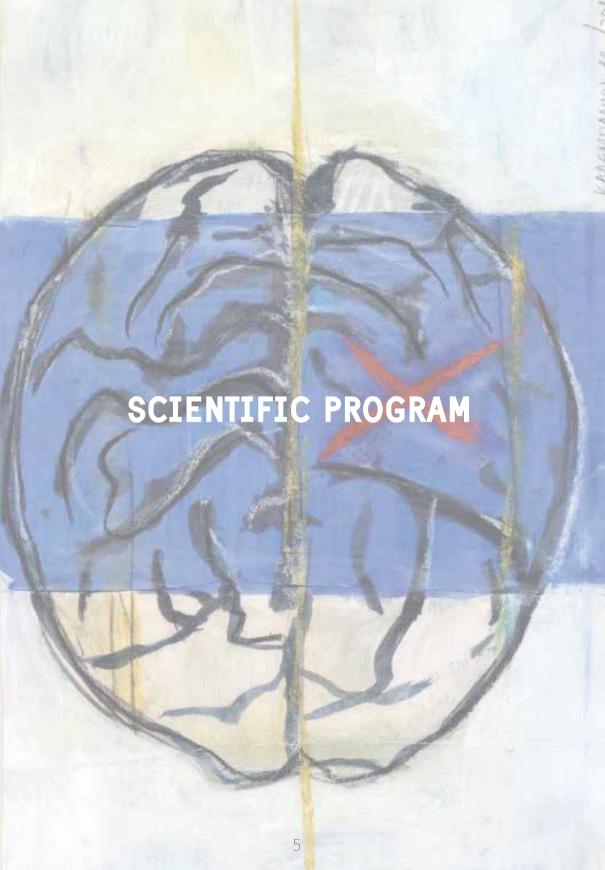
Effie Kapsalaki

Lypoulaki

Professor of Radiology, Medical School, University of Thessaly, Larissa, Greece

Kostas N. Fountas

Professor of Neurosurgery Medical School, University of Thessaly, Greece



SCIENTIFIC PROGRAM

Wednesday, 21 May 2025

08:15 - 08:30	Registrations			
Session I	Epidemiological and Histopathological Characteristics of Gliomas			
	Moderators: K. Fountas, L. Stavrinou			
08:30 - 08:50	The molecular profile of gliomas and Genetic Pathways V. Metaxa-Mariatou			
08:50 - 09:10	Histopathological considerations and classification T. Maragkou			
09:10 - 09:25	The role of molecular profiling in glioma classification T. Maragkou			
09:25 - 09:45	Biological Markers of gliomas & liquid biopsy G. M. Della Pepa			
09:45 - 10:15	The impact of novel biomarkers in clinical studies S. Short			
10:15 - 10:30	Commentary - Discussion E. Kapsalaki			
10:30 - 11:00	Coffee Break			
Session II	Basic Diagnostic Approach of Patients with Gliomas			
	Moderators: D. Kozić, J. Boban, M. Simon			
11:00 - 11:15	Conventional MRI in the initial diagnosis E. Kapsalaki			
11:00 - 11:15 11:15 - 11:30	Conventional MRI in the initial diagnosis			
	Conventional MRI in the initial diagnosis E. Kapsalaki Perfusion methods in Gliomas			
11:15 - 11:30	Conventional MRI in the initial diagnosis E. Kapsalaki Perfusion methods in Gliomas E. Papadaki MR Spectroscopy			
11:15 - 11:30 11:30 - 11:50	Conventional MRI in the initial diagnosis E. Kapsalaki Perfusion methods in Gliomas E. Papadaki MR Spectroscopy S. D. Gotsis fMRI/DII - Basics and how I do it			

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Wednesday, 21 May 2025

13:00 - 13:30	Luncheon Seminar (see page 24)		
	Neuro MR Imaging: New Technologies and Techniques Azim Celik Olympia II Hall - Main meeting room Lower Ground Floor		
13:30 - 14:45	Workshop (see page 24)		
	Advanced Neuro Magnetic Resonance Imaging (MRI) Olympia I Hall - Workshops Lower Ground Floor		
Session III	Advanced Diagnostic Approach of Patients with Gliomas Moderators: I. Seimenis, A. Zikou		
14:45 - 15:30	Applied fMRI in brain tumors H. Sair		
15:30 - 15:45	Artificial intelligence-based synthesis of contrast enhanced MRI in gliomas D. Gkotsis		
15:45 - 16:05	The role of the medical physicist I. Tsougos		
16:05 - 16:35	Radiomics / Radiogenomics N. Papanikolaou		
16:35 - 17:05	Lecture		
	Novel Treatments P. Wen		
Session IV	Interesting Cases		
	Moderators: K. Fountas, E. Papadaki		
17:05 - 18:30	P. Schucht, K. Fountas, D. Netuka, M. Thurnher, H. Sair, G. Velonakis		
19:00	Glioma Day: Public Awareness Event The event is held in Greek		

SCIENTIFIC PROGRAM

Thursday, 22 May 2025

Session V	Preoperative Evaluation and Planning				
	Moderators: T. Paleologos, P. Schucht				
08:00 - 08:20	Cortical Functional Anatomy S. Lafazanos				
08:20 - 08:40	f-MRI - Identification of eloquent cortex H. Sair				
08:40 - 09:10	Glioma cell derived circulation biomarkers: Developments for non-invasive diagnosis and therapy tracking M. Westphal				
09:10 - 09:30	APTw imaging in brain tumors P. Sundgren				
09:30 - 09:50	Integration of imaging data in surgical planning A. Kalyvas				
09:50 - 10:10	Interesting Cases M. Thurnher				
10:10 - 10:40	Coffee Break				
Session VI	Surgical Management				
	Moderators: N. Foroglou, L. Stavrinou				
10:40 - 11:10	Advanced techniques for total resection H. Duffau				
11:10 - 11:40	Preoperative brain mapping for surgery of brain tumors in eloquent areas G. Raffa				
11:40 - 12:10	Role of neuronavigation, intraoperative high field MRI and 3D US in glioma surgery D. Netuka				
12:10 - 13:10	Workshop (see page 24)				
	MRI-Guided Laser Interstitial Thermal Therapy (LITT) Olympia I Hall - Workshops Lower Ground Floor				
13:10 - 14:00	Interactive Workshop				
	Clinical Cases Moderators: P. Toulas, G. Velonakis Instructors: NA. Arkoudis, V. Barmparousi, E. Efthymiou				

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Thursday, 22 May 2025

Olympia II Hall - Lower Ground Floor

14:00 - 14:45	Light Lunch
Session VII	Surgical management - Special Surgical Techniques Moderators: K. Fountas, P. Stavrinou
14:45 - 15:15	Basic principles of glioma resection M. Sabel
15:15 - 16:00	Awake craniotomy for glioma resection M. Berger
16:00 - 16:30	Supramarginal glioma resection H. Duffau
16:30 - 17:00	Advanced cortical mapping techniques Z. Ram
17:00 - 17:30	LEATs (Long term epilepsy associated tumours) M. von Lehe
17:30 - 18:30	Video Session: How I do it Moderators: K. Fountas, G. Alexiou
	Panel: M. Berger, H. Duffau, Z. Ram, M. Sabel
19:00	Networking Cocktail Reception

Ioannis Roof Garden Bar Royal Olympic 7th floor

SCIENTIFIC PROGRAM

Friday, 23 May 2025

Session VIII	Pediatric Gliomas			
	Moderators: P. Sundgren, M. Silvera			
08:30 - 08:50	WHO classification of gliomas in children T. Maragkou			
08:50 - 09:30	Pediatric Glioneuronal tumors new and distinctive M. Silvera			
09:30 - 10:00	Neuroimaging of pediatric high grade gliomas S. Palasis			
10:00 - 10:30	Routine and advanced techniques of pediatric Gliomas A. Goldman-Yassen			
10:30 - 10:50	Neurovascular Complications in pediatric Gliomas B. Philbrook			
10:50 - 11:10	Surgical resection techniques P. Schucht			
11:10 - 11:20	The role of anti-seizure medication (ASMs) O. Schijns			
11:20 - 11:40	Commentary M. Broekman & S. Palasis			
11:40 - 12:00	Coffee Break			
12:00 - 13:15	Workshop (see page 25)			
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13:15 - 14:15	Lunch Break			

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Friday, 23 May 2025

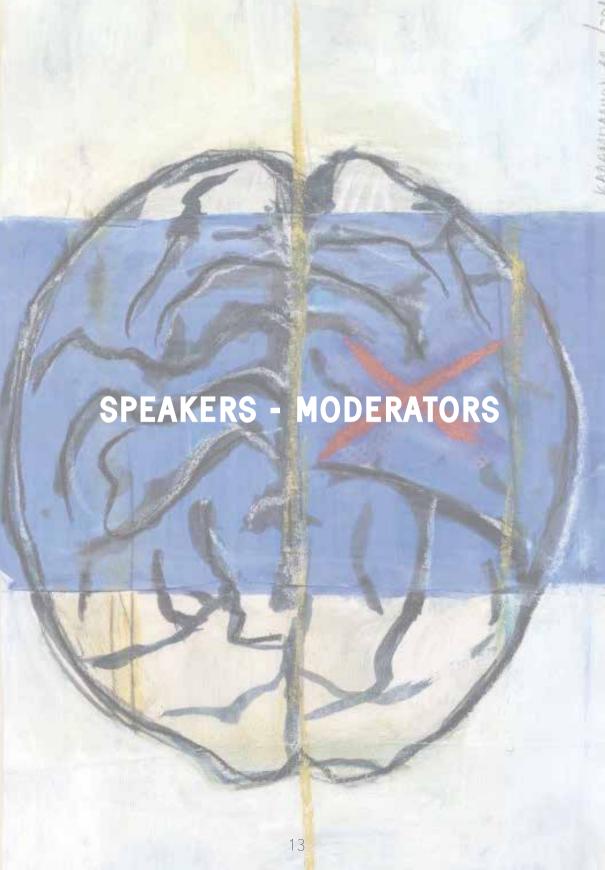
Session IX Advanced Techniques in Intraoperative Guidance				
	Moderators: S. Boviatsis, S. Korfias			
14:15 - 14:35	Neurocognitive outcome of Glioma patients M. Broekman			
14:35 - 14:55	Onco-functional Outcome in Glioma Surgery: the "gold standard" I. Solaroğlu			
14:55 - 15:25	An electrophysiological survival guide in Glioma surgery F. Sala			
15:25 - 15:55	Satellite Lecture (see page 26)			
	Low Grade Glioma: optimizing patient management in the era of precision medicine			

Session X	What's coming down the pike
	Chairs: O. Schijns, E. Kapsalaki
15:55 - 16:25	Translational Research in Glioma E. Antonio Chiocca
16:25 - 16:45	Microtumor Environment G. M. Della Pepa
16:45 - 16:55	Chemical exchange saturation transfer (CEST) I. Ioannidis
16:55 - 17:05	The next generation of nanomedicine D. Despotopoulou
17:05 - 17:20	New targets in glioma S. Short

SCIENTIFIC PROGRAM

Saturday, 24 May 2025

08:30 - 08:40	Lecture	
00.50 - 00.70	Intraoperative Neuromonitoring in Glioma Surgery: a survival quide for surgeons	
	M. Campos	
08:40 - 09:30	Workshop (see page 25)	
	Intraoperative Brain Mapping: How to do it? Olympia 1 - Works Lower Ground	hops
Session XI	Adjuvant treatment	
	Moderators: K. Barkas, A. Zygogianni	
09:30 - 09:50	Neurocognition and gliomas E. Liouta	
09:50 - 10:10	Advanced post-operative imaging and treatment response V. Katsaros	
10:10 - 10:30	Radiation treatment C. Boskos	
10:30 - 10:50	Stereotactic radiosurgery M. Piperis	
10:50 - 11:35	Systemic therapy E. Razis	
11:35 - 12:00	A sarterian view on the clinical research for treatment of GBM ${\bf Z.\ Ram}$	
12:00 - 12:20	The adverse effects of radiotherapy on healthy brain J. Boban	
Session XII	Challenging Cases submitted by the participants	
	Moderators: E. Kogias, A. Kalyvas	
12:20 - 13:20	Panel: P. Schucht, Z. Ram, M. Sabel, F. DiMeco	
13:20	Closing Remarks	



SPEAKERS - MODERATORS

Georgios Alexiou	Assistant Professor of Neurosurgery, University of Ioannina,
	Greece

Nikolaos-Achilleas Arkoudis

MD, MSc, PhD, EDiR, Consultant Radiologist, Research Unit of Radiology and Medical Imaging, National and Kapodistrian University of Athens, Greece, 2nd Department of Radiology, General University Hospital "Attikon", National and

Kapodistrian University of Athens, Greece

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Vasiliki Barmparousi

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Athens, Greece

Mitchel S. Berger MD, FACS, FAANS, Berthold and Belle N. Guggenhime Professor,

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1997-2020, Department of Neurological Surgery, USA

Jasmina Boban Assistant Professor, Department of Radiology, Faculty of

Medicine, University of Novi Sad, Vojvodina Institute of

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Christos Boskos Radiosurgeon/Radiation-Oncologist, Hellenic Neuro-Oncology

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Arkana Forum, Germany

E. Antonio Chiocca Harvey W. Cushing Professor of Neurosurgery, Harvard

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Society for Neuro-oncology, American Academy of Neurological

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Giuseppe Maria Della Pepa

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Despoina Despotopoulou

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Adam Goldman-Yassen

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PhD, Free Lance MRI Specialist, Greece

Ioannis Ioannidis

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SPEAKERS - MODERATORS

sto			

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Professor of Radiology, Medical School, University of Thessalv, Larissa, Greece

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Vasiliki Metaxa-Mariatou

Molecular Biologist, M.Sc., Group Leader of Somatic Genomic Panels & Quality Assurance Manager, Genekor Medical S.A.

David Netuka

MD, PhD, Professor, Chairman, Department of Neurosurgery and Neurooncology, 1st Medical Faculty, Charles University, Central Military Hospital, Prague, Czech Republic

Susan Palasis

MD, Professor of Radiology and Pediatrics, Emory University School of Medicine, Director of Pediatric Neuroradiology, Children's Healthcare of Atlanta, Georgia, USA, Past President of the American Society of Pediatric Neuroradiology

Theofilos S. Paleologos

MD, FRCS, Consultant Neurosurgeon, Head of Neurosurgery Department, General Hospital of Nikaia -Piraeus, Athens, Greece

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PhD, Research Group Leader, Clinical Computational Imaging Group @ Champalimaud Research, Lisbon, Portugal, Machine Learning Imaging Lead, AI Hub, @ Royal Marsden Hospital, London, UK, Honorary Reader @ Institute of Cancer Research, London, UK, Affiliated Researcher, Archimedes Unit, Athena RC, Athens, Greece, Affiliated Researcher, Institute of Computer Science, FORTH, Heraklion, Greece

Bryan Philbrook

MD, Associate Professor, Emory Department of Pediatrics, Director, Emory/CHOA Pediatric Stroke & Neurovascular Program, Pediatric Neurology, Epilepsy and Clinical Neurophysiology, Children's Healthcare of Atlanta, Georgia, USA

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MD, PhD, Radiation Oncologist, Assistant Director, Iatropolis Radiosurgery Center - CyberKnife, Athens, Greece

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SPEAKERS - MODERATORS

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Ioannis Seimenis Professor of Medical Physics, School of Medicine, National

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President, British Neuro Oncology Society (BNOS)

V. Michelle Silvera

MD, Chief Pediatric Neuroradiology, Associate Professor
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Marec von Lehe

Professor, Head of Department of Neurosurgery, Brandenburg Medical School, Germany

SPEAKERS - MODERATORS

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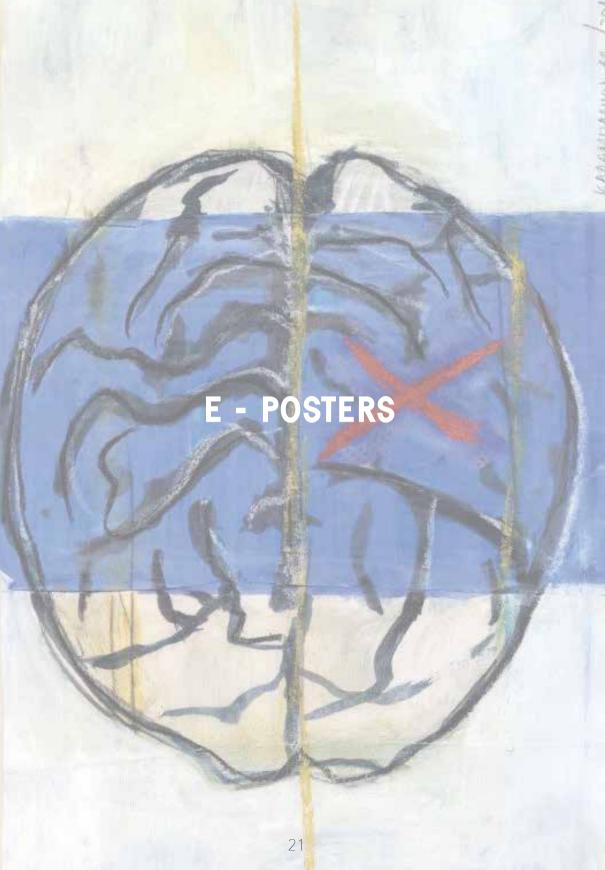
Anastasia Zikou Associate Professor of Radiology, Medical School,

University of Ioannina, Greece

Anna Zygogianni Associate Professor of Radiation Oncology, Aretaieion

University Hospital, National and Kapodistrian

University of Athens, Greece



F - POSTERS

PP 01

BRCA MUTATIONS: SHOULD WE CHECK ABOUT GLIOMAS? A CASE REPORT AND A LITERATURE REVIEW

Papachristou A., Papoutsakis D., Lipiridis S., Pana A., Nikova A., Papadakos D., Makrygiannakis G., Gogos C.

Neurosurgery Department, General Hospital Asklepieio Voulas, Athens, Greece.

PP 02

NEUROSURGERY 2.0: EMERGING AI APPLICATIONS IN GLIOMA SURGERY

Boulieris S.1, Karaferi M. E.2, Papadakos D.1,3

- ¹ Faculty of Medicine, University of Patras, Greece
- ² School of Medicine, National and Kapodistrian University of Athens, Greece
- ³ Department of Neurosurgery, General Hospital "Asklepieio" Voulas, Athens, Greece

PP 03

AVOIDING FALSE INTRAOPERATIVE FLUORESENCE IN 5-ALA GUIDED RESECTION OF HIGH-GRADE GLIOMAS

<u>Politis A.</u>¹, Stavrinou L.¹, Lani E.¹, Zemperligkos P.¹, Kalyvas A.^{1,3}, Papadopoulos E.¹, Banos S.¹, Gavra M.², Savvanis G.¹, Ydreos I.¹, Boviatsis E.¹

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- ² Department of CT and MRI Imaging, "Agia Sofia" Hospital, 11527 Athens, Greece
- ³ Division of Neurosurgery, Department of Surgery, Temetry Faculty of Medicine, University of Toronto, Toronto, Canada

PP 04

OPTIMIZATION OF BRAIN SURGICAL PLANNING USING ARTIFICIAL INTELLIGENCE AND RADIOGENOMICS METHODS

Georgiadis I.1,5, Kapsalaki E.2, Satra M.3, Tsougos I.4, Fountas K.5

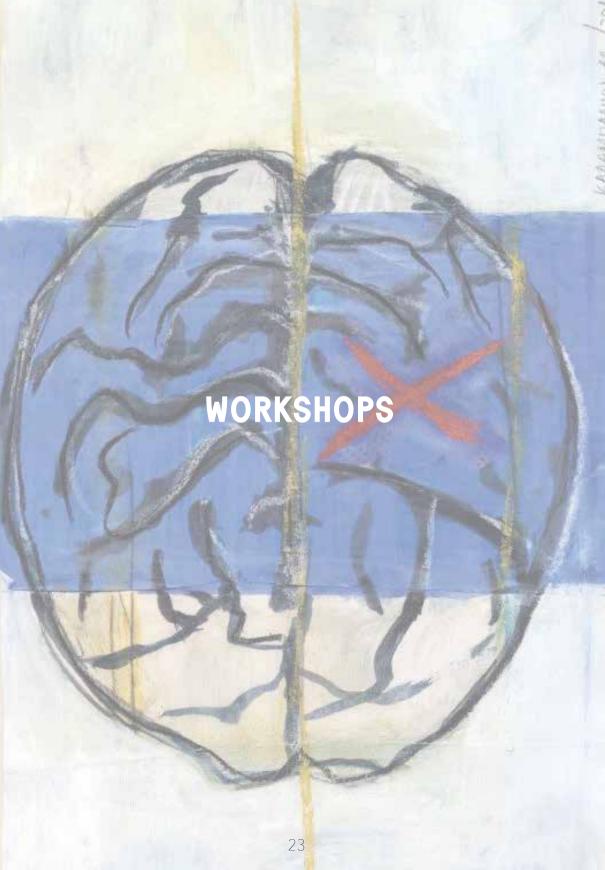
- ¹ lst Neurosurgical Department, IASO Thessalias, Larissa, Thessalv Greece
- ² Department of Radiology, Faculty of Medicine, University of Thessaly, Greece
- ³ Department of Molecular Biology and Genetics, Faculty of Public and One Health, University of Thessaly, Greece
- ⁴ Department of Medical Physics, Faculty of Medicine, University of Thessaly, Greece
- ⁵ Department of Neurosurgery, Faculty of Medicine, University of Thessaly, Greece

PP 05

AWAKE CRANIOTOMY FOR GLIOMAS: REDEFINING THE LIMITS FOR SAFE RESECTION

Karaferi M.E.1, Boulieris S.2, Fountas K.3

- ¹ School of Medicine, National and Kapodistrian University of Athens, Greece
- ² Faculty of Medicine, University of Patras, Greece
- ³ Neurosurgical Department, Larissa University Hospital, Larissa, Greece



WORKSHOPS

Wednesday, 21 May 2025



Luncheon Seminar 13:00 - 13:30

Olympia II Hall - Main meeting room Lower Ground Floor

Neuro MR Imaging: New Technologies and Techniques

Azim Celik | Research and Development Manager, GE HealthCare

Workshop 13:30 - 14:45

Olympia I Hall - Workshops Lower Ground Floor

Advanced Neuro Magnetic Resonance Imaging (MRI)

Advanced Magnetic Resonance Imaging (MRI) methods such as Spectroscopy, Diffusion Weighted Imaging (DWI) and Diffusion Tensor Imaging (DTI), Time Course series, and Functional Imaging have significantly improved the ability to image conditions of the brain. Beyond conventional anatomic and structural data, these advanced techniques provide physiological information on metabolism and hemodynamics.

Thursday, 22 May 2025

Medtronic

Workshop 12:10 - 13:10

Olympia I Hall - Workshops Lower Ground Floor

MRI-Guided Laser Interstitial Thermal Therapy (LITT)

A minimally invasive approach for brain tumors, epilepsy and radiation necrosis.

Thursday, 22 May 2025

Interactive Workshop 13:10 - 14:00

Olympia II Hall - Main meeting room Lower Ground Floor

Clinical Cases

Moderators: P. Toulas, G. Velonakis

Instructors: N.-A. Arkoudis, V. Barmparousi,

E. Efthymiou

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Friday, 23 May 2025



Workshop 12:00 - 13:15

Olympia I Hall - Workshops Lower Ground Floor

Hands on Advanced Imaging Processing Techniques

Themis Boursianis | Application Specialist MR / Medical Physicist, Siemens Healthineers

Discussion of interesting imaging cases from A to $\ensuremath{\mathsf{Z}}$

E. Kapsalaki - S. D. Gkotsis

Saturday, 24 May 2025



Lecture 08:30 - 08:40

Olympia II Hall - Main meeting room Lower Ground Floor

Intraoperative Neuromonitoring in Glioma Surgery: a survival guide for surgeons

Dr. Marianella Campos | Neurosurgeon and IONM Specialist, Medical Director at Arkana Forum, Germany

Workshop 08:40 - 09:30

Olympia I Hall - Workshops Lower Ground Floor

Intraoperative Brain Mapping: How to do it?

- What kind of monitoring is needed?
- Reasons for cortical stimulation and mapping
- Areas to locate
- Methods used





Low Grade Glioma:

Optimizing patient management in the era of precision medicine



Friday, May 23rd 2025 (15:25-15:55)



Royal Olympic Hotel, Athens, Greece

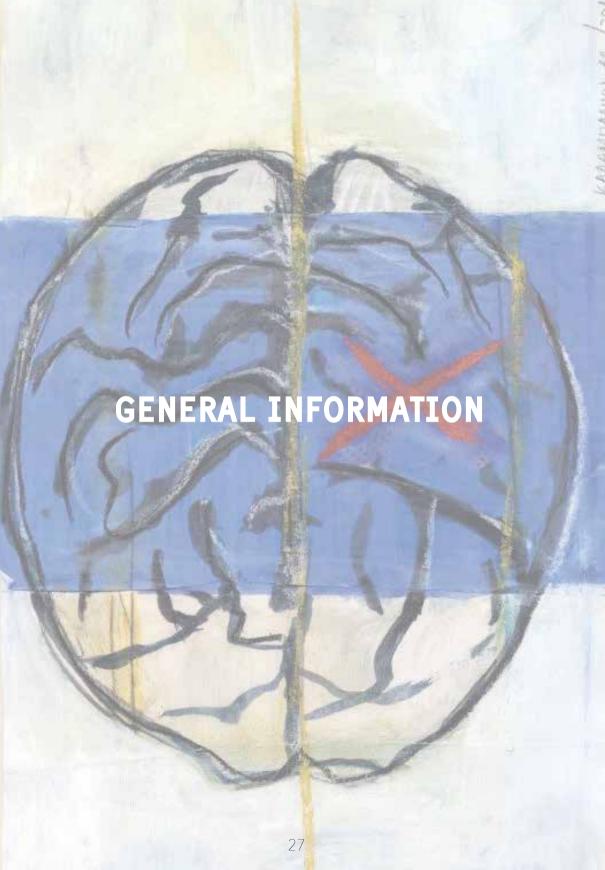
Speaker

Evangelia Razis MD, PhD

Director 3rd Oncology Department, Director Contemporary Oncology Team "Hygeia" Hospital, Athens, Greece



Intracranial Glioma Workshop: From A to 21-24 May 2025 / Athens Greece **Organizer: Hellenic Neurosurgical Society**



GENERAL INFORMATION

OR CODES FOR MEETING ATTENDANCE

Each registered participant will receive an e-mail with their personal QR code, in order to attend the scientific program. Each participant will need to scan their QR code upon entrance and exit of the scientific sessions hall. Only participants that have received a QR code will be allowed in the meeting areas.

CERTIFICATE OF ATTENDANCE

Participants will receive their certificate of attendance by e-mail, within 1 week after the end of the meeting, after having completed the electronic evaluation. Attendance of at least 60% of the scientific program is mandatory in order to receive the certificate of attendance (19 hours).

PRESENTATIONS RECEPTION DESK

The presentations reception desk will be available for the duration of the meeting to receive the speakers' presentations. It is located inside the main meeting room Olympia II at the Lower Ground Floor. Speakers are required to deliver their presentations (USB stick) on-time, at least one (1) hour before the start of their presentation.

EXHIBITION

The exhibition is located at the foyer of Olympia Hall, next to the main course hall, Olympia II Hall at the Lower Ground Floor.

LANGUAGE

English is the official language of the workshop. There will be no simultaneous translation.

SECRETARIAT SERVICE HOURS

Wednesday, 21 May 2025	08:00 - 19:00
Thursday, 22 May 2025	07:30 - 18:30
Friday, 23 May 2025	08:00 - 17:20
Saturday, 24 May 2025	08:00 - 13:20

CME CREDITS

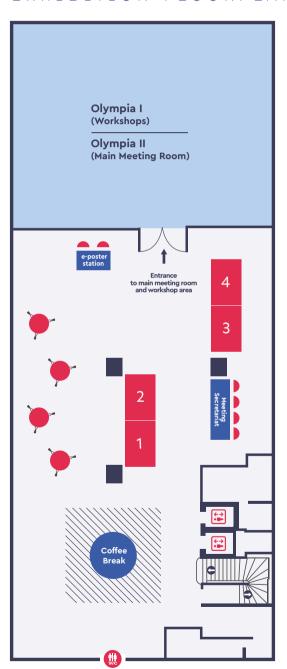
The INTRACRANIAL GLIOMA WORKSHOP: From A to Z, Athens, Greece, 21/05/2025-24/05/2025 has been accredited by the European Accreditation Council for Continuing Medical Education (EACCME®) with **23.5 European CME credits** (ECMEC®s).

Each medical specialist should claim only those hours of credit that he/she actually spent in the educational activity. Through an agreement between the Union Européenne des Médecins Spécialistes and the American Medical Association, physicians may convert EACCME® credits to an equivalent number of AMA PRA Category 1 Credits™. Information on the process to convert EACCME® credit to AMA credit can be found at https://edhub.ama-assn.org/pages/applications. Live educational activities, occurring outside of Canada, recognized by the UEMS-EACCME® for ECMEC®s are deemed to be Accredited Group Learning Activities (Section 1) as defined by the Maintenance of Certification Program of the Royal College of Physicians and Surgeons of Canada.

21 22 M A Y 23 24 2025 ATHENS, GREECE



EXHIBITION FLOORPLAN



Booth	Number		
Neuraxon/ Filippos Healthcare	1		
Mart Hellas	2		
Designs for Vision/ Medical Evolution	3		
GE Healthcare	4		

ACKNOWLEDGMENTS

The Organizers would like to thank all sponsors and exhibitors for their contribution and active involvement in the success of the workshop.

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ABOUT US

MAKRIS S.A. is a Greek industrial company specializing in the production of metal cladding systems for buildings. Since its founding in 1978 in Larissa, it has earned a leading position in the Greek market and the wider region, while staying true to the values of a family-owned business.

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At MAKRIS, we believe that true progress is not only measured in industrial innovation but also in our commitment to people and society. Supporting the INTRACRANIAL GLIOMA WORKSHOP reflects our deep respect for the medical community and our solidarity with those affected by serious health challenges.

Through this sponsorship, we aim to contribute to advancing scientific knowledge and improving human lives.

OUR VISION

We envision a world where buildings are defined by aesthetic refinement, structural resilience, and environmental responsibility. We are driven by the belief that architectural envelopes should not only protect and endure but also elevate the built environment, combining technical performance with inspiring design.

Our core values guide every decision we make and reflect our steadfast commitment to providing solutions that meet the most demanding standards. We focus on creating long-term value by fostering trust with our clients and partners, while continually advancing our products and services through innovation.

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 ΟΝΟΜΑΣΙΑ ΤΟΥ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΪΟΝΤΟΣ Gadovist 1,0 mmol/ml ενέσιμο διάλυμα σε προγεμισμένη σύργγο/ φυσίγ-γιο 2. ΠΟΙΟΤΙΚΗ ΚΑΙ ΠΟΣΟΤΙΚΗ ΣΥΝΘΕΣΗ 1 ml ενέσιμου διαλύματος περίεχει 604,72 mg γαδοβουτρόλης (ροοδύναμο με 1,0 mmol γαδοβουτρόλης που περίεχει 15,22 mg γαδοδύνω). 1 προγεμισμόνη σύργης με 5,0 ml περίεχει 302,3 mg γαδοβουmmal γαοθρουτρόλης που πρείχει 157,25 mg γαοδολινού, 1 προγειμομένη ούρηνης με 5,0 ml περιέχει 3.023,6 mg γαοδοβουτρόλης. Τρογειμομένη ούρηνης με 16 ml περιέχει 3.023,6 mg γαοδοβουτρόλης. 1 προγειμομένη ούρηνης με 16 ml περιέχει 6.047,2 mg γαοδρουτρόλης. 1 προγειμομένη ούρηνης με 15 ml περιέχει 9.070,8 mg γαοδρουτρόλης, 1 προγειμομένη ούρηνης με 15 ml περιέχει 9.070,8 mg γαοδρουτρόλης, 1 φοιγήνης με 15 ml περιέχει 9.070,8 mg γαοδρουτρόλης, 1 φοιγήνης με 15 ml περιέχει 9.070,8 mg γαοδρουτρόλης, 1 φοιγήνης με 15 ml περιέχει 9.070,8 mg γαοδρουτρόλης, 1 φοιγήνης με 15 ml περιέχει 18.14,16 mg γαοδρουτρόλης, 1 φοιγήνης με 15 ml περιέχει 18.14,16 mg γαοδρουτρόλης, 1 φοιγήνης με 30 ml περιέχει 18.14,16 mg γαοδρουτρόλης, 1 ένα πρείχει 12.094,4 mg γαοδρουτρόλης, 1 φοιγήνης με 30 ml περιέχει 18.14,16 mg γαοδρουτρόλης. Εκδοχρ με γαναιτέχει 10.095 ml πρείχει 12.094,4 mg γαοδρουτρόλης, 1 φοιγήνης με 30 ml περιέχει 18.14,16 mg γαοδρουτρόλης. 1 ένα πρείχει 10.095 ml φαρμακευτικό προύν προσίζεται για σύσφάββια γορήγηση μένα. Η αποιτούμενη δόση χορηκείται αλλοφάβία ως ταχεία ένεση εφόδου (bouls, Η ενισχιαμένη με σκισγραφόκα Μέ) μισιαν έα ξεκινθεία αμέσως ττό δε ούτυρο διάστημα μετά την ένεση ανάλογα με τις ακολουθίες των παλών που χρησμοποιούνται και με το πρωτόκολο της εξέτασης. Η βάλτιστη ενίσχυση σήματος πραστηρείται κατά την αρτηριακή πρώτη δίσθο για την CE-MPA και μέσα σε διάστημα πρέπου 15 λε-πτών μετά την ένεση του Gadovist για τις ενδείξεις του ΚΝΕ (ο χρόνος εξαρτάται από τον τύπο της βλάβης/του ιστού). Οι ακολουθίς Τ.1 προσανατολισμού έναι Ιούτερα και καλάληλες για εξείτασε με σιακροφικά. Η ενδοσγγειανή χρόγηση του οιακροφικών μέσων πρέπει να γίνεται, είνε είναι δύναντόν, με τον ασθενή ξαπλωμένο. Μετά τη χρόγηγηση, α οιθενής πρέπει να παρακολουθέται για τουλάγιστον μισή ώρα, ακούς η μπιερία δείγεν ότι τη πλειογήθα των ανεπιθέμητων ενεργειών παρατηρείται μέσα σε αυτό το λάστημα (βλέπε παράγραφο 4.4). Οληγίες χρήσης: Το προίνα αυτό προσίζεται μένον για μία χρήση. Αυτό το Αφαρικεντική οποίνε πρέπει το ανεπιθέρε το του ποθενή ξαπλωμένο. Μετά τη χρόγηγηση, το προίνα μετά προχειαμένη συλγινα πρέπει να αφαιρείται από την προγεισμένη ή διαντωμετικόν περιέκτη. Προγειμομέ-γες σώρχης Η πορογεισμένη συλγινα πρέπει να αραφοριέται από την προγεισμομένη ούργηνα αμέσως προν από της χρήση. Αυτό το Πορογεισμένη συλγινα πρέπει να ελαφισμέτα από την προγεισμένη σύργηνα αμέσως προν από της χρόγη του Ενδείζεται για το Αναφοριέται από την προγεισμένη σύργηνα αμέσως προν από τη χρόγη, Φυ-σύρχα Η χρόγηγηση η Εύσων σκαγογράφικής αντίθεσης του χρομένται τα τη συνεισμένε το αναφοριάς του προγεισμένη το καιδιακό της του παραγραφόκης αντίθεσης του χρομένται τα τη συνεισμένε που συλγείζεται να χυτοι αναφορικής αντίθεσης του αναφορφορικής αντίθεσης του χρονής των τα προγραφορικής αντίθεσης του αναφορικής αντίθεσης του αναφορικής αντίθεση το είναι το το του του αντίθεση το προγεισμένη το το αναφορικού την τη συνεισμένε το υπολύγεται με θεσή το το μοιφορικό δια τινα τισμένε το τι

λώνουν βλάβη στη γονιμότητα. **4.7 Επιδράσεις στην ικανότητα οδήγησης και χειρισμού μηχανημάτων** Δεν εφαρμόζεται. **4.8 Ανεπθύμητες ενέργειε** Το συκολικό προφίλ ασφαλείας του Gadovist βασίζεται σε δεδομένα από περισσότερους από 6.300 ασθεγεία που συμμετείχου κα κλινικές όσωιξες και από την παρακολύθηση του προίδτος μετά την κλινικόρορία του 6.300 αθένεις που συμμετείραν σε κλυπιές λουμίες, και από την πορακολούθηση του προϊόντος μετά την κυκλοφορία του την αγορό. Ο πιο πογική πρατηρισμένες φεπθιμίνητες ενέγεγειες σε ασθενείς που πορία πρατηρισμένες αντιθιμίνητες ενέγεγειες σε ασθενείς που λαμβάνουν Gadovist είναι εκφολαλίγα, ναυτία και ζάλη. Ο πιο οσθορές αντιθιθιμητες ενέγεγειες σε ασθενείς που λαμβάνουν Gadovist είναι εκφολασή ανακοπή, ανάγορο ο όξειος αναντευτικής δυσερέσεις. Γιντευριονικό οθόμη και σοδρορές αντιφιλούσεις τός αντιθιμένητες ενέγειες σε ασθενείς που λαμβάνουν Gadovist είναι εκφολασίς (συμπερλόβονομένης της αναπινευτικής ανακοπής και του αναφιλοκτικού σου), Καθιστερημένες αναφιλοκτισούσεις αντιβορίας ή κόλες (πουστερηθένα) ανακοπής αντιβορίας ή κόλες (πουστερηθένεις αντιβονείς ή κόλες (πουστερηθένεις αντιβονείς η κόλες (πουστερηθένεις αντιβονείς τους αντιβονείς αντιβονείς αντιβονείς αντιβονείς τους αντιβονείς αντιβονείς αντιβονείς αντιβονείς αντιβονείς τους αντιβονείς αντιβονείς αντιβονείς τους αντιβονείς
Πίνακας 1: Ανεπιθύμητες ενέργειες που αναφέρθηκαν σε κλινικές δοκιμές ή κατά τη διάρκεια της παρακολούθησης Του προϊόντος μετά την κυκλοφορία του, σε αρβενείς που έλαβαν Gadovist

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Κατηγορία Οργανικού Συστήματος	Συχνές	Όχι Συχνές	Σπάνιες	Μη γνωστές	
Διαταραχές του ανοσο- ποιητικού συστήματος		Αντόροση υπερευσιθησίας! αναφιλιακτοιούς αντίδροση. # (π.χ. αναφιλιακτοιούς αντίδροση. # (π.χ. αναφιλιακτοιούς αντίδροση. # (π.χ. αναφιλιακτοιούς αντίδροση. # (π.χ. αναφιλιακτοιούς αναφιλια			
Διαταραχές του Νευρικού Συστήματος	Κεφα- λαλγία	Ζάλη, Δυσγευσία, Παραισθησία	Απώλεια συνειδή- σεως*, Σπασμοί, Παροσμία		
Καρδιακές διαταραχές			Ταχυκαρδία, Αίσθημα παλμών	Καρδιακή ανακοπή*	
Διαταραχές του ανα- πνευστικού συστήματος, του θώρακα και του μεσοθωράκιου		Δύσηνοια*		Σύνδρομο οξείας αναπνευστικής δυ- σχέρειας (ΣΟΑΔ)*1, Πνευμονικό οίδημα*1	
Διαταραχές του γαστρε- ντερικού συστήματος	Ναυτία	Έμετος	Ξηροστομία		
Διαταραχές του δέρματος και του υποδόριου ιστού		Ερύθημα, Κνησμός (συμπεριλαμβανομένου του γενικευμένου κνησμού), Εξάνθημα (συμπεριλαμβανομένου του γενικευμένου, κηλιδώδους, βλατιδώδους, κνησμώδους εξανθήματος		Νεφρογενής Συστηματική Ίνωση (ΝΣΙ)	
Γενικές διαταραχές και καταστάσεις της οδού χορήγησης		Αντίδραση στο σημείο της ένεσης°, Αίσθημα καύσου	Αίσθημα κακουχίας Αίσθημα ψύχους		

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λατίξο αυταθούμες της δοδο ευθύνη για το χούν ο φύλλαξης κατά τη χρήση και τις συνθήκες φύλλαξης που προηγούνται της χρήσης. 6.4 Ιδιαίτερες προφωλάζεις κατά τη φύλλαξη του προύντος Το φοριμακτυκό αυτό προύν δεν ο παπεί πάπετερς συνθήκες φύλλαξης. Του τος συνθήκες φύλλαξης του ανοημένου φαρμακευτικού προϊάντος βλέπει πραφηραφό 6.3. 6.5 Φύση και συστατικά του περίε κτης Τυάλληςς συγγες διαλογομενής λία το περίε της το πλειάν το μετά το κατά το πολογομένη σύργης το Περία ποιδιαίνη το Περία ποιδιαίνη το Περία ποιδιαίνη το Μετά το πόμε το περία ποιδιαίνη το Μετά το πόμε το περία ποιδιαίνη το Επεία πόμε από το περία ποιδιαίνη το Απεία πόμε το περία ποιδιαίνη το Επεία πόμε το Απεία πόμε το Απεία ποιδιαίνη το Απεία ποιδια





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ΣΥΝΟΠΤΙΚΗ ΠΕΡΙΓΡΑΦΗ ΤΩΝ ΧΑΡΑΚΤΗΡΙΣΤΙΚΩΝ ΤΟΥ ΠΡΟΪΟΝΤΟΣ

ΟΝΟΜΑΣΙΑ ΤΟΥ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΪΟΝΤΟΣ: Ivor 2.500 IU antiXa/0,2 ml ενέσιμου διαλύματος σε προγεμισμένες σύριγγες ΠΟΙΟΤΙΚΗ & ΠΟΣΟΤΙΚΗ ΣΥΝΘΕΣΗ: Bemiparin sodium: 2.500 IU (anti Factor Xa*) ανά πl eνέσιμου διαλύματος. Η δραστικότητα περιγράφεται σε Διεθνείς μονάδες απτί-Factor Xa*) ανά πl evέσιμου διαλύματος. Η δραστικότητα περιγράφεται σε Διεθνείς μονάδες απτί-Factor Xa*) ανά προγεμισμένες σύριγγες. (ΠΟΙΟΤΙΚΗ & ΠΟΣΟΤΙΚΗ ΣΥΝΘΕΣΗ: Bemiparin sodium: 2.500 IU anti-Xa/0,2 ml BT x 2 PFSYR Λ.Τ.: 5,83 €

ΟΝΟΜΑΣΙΑ ΤΟΥ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΪΟΝΤΟΣ: Ivor 3.500 IU antiXa/0,2 ml ενέσιμου διαλύματος σε προγεμισμένες σύριγγες, ΠΟΙΟΤΙΚΗ & ΠΟΣΟΤΙΚΗ ΣΥΝΘΕΣΗ: Bemiparin sodium: 3.500 IU (anti Factor Xa*) ανά 0,2 ml προγεμισμένη σύριγγα (ισοδύναμη με 17.500 IU (anti Factor Xa*) ανά πl ενέσιμου διαλύματος. Η δραστικότητα περιγράφεται σε Διεθνείς μονάδες απτί-Factor Xa*) ανά 0,2 ml προγεμισμένη σύριγγα (Ι/U) με βάση το Πρώτο Διεθνές Πρότυπο Αναφοράς. Ηπαρίνης Χαμηλού Μοριακού Βάρους, Για τον πλήρη κατάλογο των εκδόχων, βλ. παράγραφο 6.1. ΣΥΣΚΕΥΑΣΙΕΣ/ΤΙΜΕΣ: IVOR 3.500 IU anti-Xa/0,2 ml BT x 2 PFSYR Λ.Τ.: 10,74 BT x 30 PF.SYR Λ.Τ.: 120,83 €

ΟΝΟΜΑΣΙΑ ΤΟΥ ΦΑΡΜΑΚΕΥΤΙΚΟΥ ΠΡΟΪΟΝΤΟΣ: Ivormax 25.000 IU (anti-Factor Xa*) ανά σ.Σ προγεμισμένη σύριγγα, 7.500 IU (anti-Factor Xa*) ανά σ.Σ προγεμισμού διαλύματος σε προγεμισμένη σύριγγα, 7.500 IU (απτί-Factor Xa*) ανά σ.Σ προγεμισμού διαλύματος σε προγεμισμένη σύριγγα, 7.500 IU (απτί-Factor Xa*) ανά σ.Σ προγεμισμένη σύριγγα, 7.500 IU (απτί-Factor Xa*) ανά σ.Σ προγεμισμένη σύριγγα, 7.500 IU (απτί-Factor Xa*) ανά σ.Σ προγεμισμένη σύριγγα. Το Προγεμισμένη σύριγγα, 7.500 IU (απτί-Factor Xa*) ανά σ.Σ προγεμισμένη σύριγγα. ΤΕΣ ΜΕΣ ΕΧΕΣΕΥΤΙΜΕΣ: IVORΜΑΧ 25.000 IU απτί-Xa/ml, ΒΤΧΣΡΕΣΥΚΕΥΑΣΙΕΣ/ΤΙΜΕΣ: IVORΜΑΧ 25.000 IU απτί-Xa/ml, ΒΤΧΣΡΕΣ ΧΕΧΕΥΑΣΙΕΣ/ΤΙΜΕΣ: IVORΜΑΧ 25.000 IU απτί-Xa/ml, ΒΤΧΣΡΕΣ ΧΕΧΕΥΑΣΙΕΣ/ΤΙΜΕΣ: IVORΜΑΧ 25.000 IU απτί-Xa/ml, ΒΤΧΣΡΕΣ/ΣΚΟ,ΔΑΙΕ, Λ.Τ.: 23,43€ (ΝΟΡΜΑΣ) 25.000 IU απτί-Xa/σε (Σ.Σ ΕΧΕΣΙΕΣ/ΤΙΜΕΣ) ΙΝΟΡΜΑΣ 25.000 IU απτί-Xa/ml, ΒΤΧΣΡΕΣ/ΣΚΟ

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The ACTION Study



Dordaviprone (ONC201) in newly diagnosed H3 K27M-mutant diffuse glioma

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- The H3 K27M mutation occurs in both pediatric and adult patients with glioma^{1,2}
- Dordaviprone, a first-in-class imipridone, is a selective small molecule agonist of ClpP and antagonist of DRD2

The ACTION study (NCT05580562) is a randomized, double-blind, placebo-controlled, parallel-group international Phase 3 trial of patients with newly diagnosed, H3 K27M diffuse glioma after completion of radiotherapy.

Eligibility Criteria

- H3 K27M-mutant diffuse glioma, H3 K27M mutation by IHC or NGS
- ≥10 kg body weight
- Completed radiotherapy within 2 to 6 weeks prior to randomization
- KPS/LPS ≥70
- · Stable or decreasing corticosteroids and anti-seizure medication for seven days
- Not eligible: Spinal tumors, DIPG, leptomeningeal spread, CSF dissemination

1:1:1 Randomization (2–6 weeks post RT)

Dordaviprone (625 mg) Twice-weekly Dordaviprone (625 mg) Once-weekly

Placebo

Eligibility will not be restricted based on age, provided patients are ≥10 kg.

Patients ≤52.5 kg will receive a dose scaled by body weight.

Primary Outcomes:

Efficacy: OS, PFS

Study Status:

- ACTION is open at more than 140 centers globally and is enrolling throughout Europe, Israel, South America, and Asia-Pacific.
- An up-to-date list of study sites is available at clinicaltrials.gov (NCT05580562).
- Funding is available for eligible patients who must travel for treatment; contact clinicaltrials@chimerix.com for more information.

Dordaviprone is an investigational drug currently undergoing clinical development and has not been approved for sale by regulatory health authorities.

References

1. Lulla RR, et al. Sci Adv. 2016;2(3):e1501354

2. Khuong-Quang DA, et al. Acta Neuropathol. 2012;124(3):439-47





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