2024

II INTERNATIONAL WORKSHOP

MANAGEMENT, INNOVATION, AND ASSESSMENT OF HEALTH TECHNOLOGIES IN MEDICAL DEVICES

Free Event

SCHEDULE

OCTOBER, 25th and 26TH

Hybrid / Simultaneous Translation

IB EVENTS SPACE AMPHITHEATER

UNESP BOTUCATU CAMPUS - SÃO PAULO - BRAZIL

Debjani Mueller

She is a Senior Researcher at Charlotte Maxeke Medical Research Cluster (CMeRC) in Johannesburg. She currently holds a faculty position with University of Pretoria in South Africa and is a doctoral candidate at the Technical University of Berlin. Over the last decade, she has gained practical experience in evaluating medical devices as part of her work with the CMeRC team and shared her experience through training throughout South Africa and other parts of the world through distance-based education. She has taught hospital managers in South Africa (MPH in Hospital management) as an initiative of the EU and South African Department of Health. Her research focuses on advancing the methods used in the area of medical device assessment to enhance its usefulness in the context of real-world decision-making which involves taking a life-cycle approach to medical technology assessment. Jani continues to focus her effort on promotion, collaboration and raising awareness of sustainable HTA development and implementation. She was a founding member of South African HTA Society (SAHTAS), has been a director on the INAHTA Board since 2013, and is currently the chair of the HTAi Interest Group on developing Countries. She has served on the International Scientific Program Committee of HTAi's Annual Meeting over the years and more recently is an Associate Editor of IJTAHC. Furthermore, she has been co-opted as a Board member by the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) South Africa Chapter Board for the term 2018-2019. Jani nurtures a keen interest in building competencies and education and training in HTA, especially in emerging settings. She has published and co-authored a number of articles, contributed to book chapters and presented her research findings to an array of scientific audiences.

Ernesto Iadanza

Ernesto Iadanza, Ph.D., Senior Assistant Professor (tenure-track, RTD-b) at the Department of Medical Biotechnologies, University of Siena, Italy. National qualification as Associate Professor in Bioengineering.

He is currently a member of the IFMBE Administrative Council, chair of the Council of Societies of the International Federation for Medical and Biological Engineering (IFMBE), immediate past chair of its Health Technology Assessment Division Board (IFMBE/HTAD), and past chair of its Clinical Engineering Division Board (IFMBE/CED).

Member of the Union Journal Committee of the International Union for Physics and Engineering in Medicine (IUPESM).

He is also IEEE (and IEEE-EMBS) Senior Member and received the IBM Faculty Award in 2013, the IFMBE/CED Teamwork Award in 2019, the IFMBE/CED Best Journal Article Award 2022 and the IFMBE/CED Best Conference Paper Award 2022.

Section Editor of "Technology and Health Care", Associate Editor of "PLOS One", "Frontiers in Bioengineering and Biotechnology", "Health & Technology", and "Future Internet" and member of the scientific committee of many international conferences in bioengineering.

Dr. Iadanza is the organiser of postgraduate master courses in Clinical Engineering, Healthcare Engineering and HTA at the University of Florence since 2007.

Supervisor in 200+ graduation theses. Author of 190+ publications on international books, scientific journals, volumes and conference proceedings.Editor in Chief, Clinical Engineering Handbook 2nd Edition, Academic Print.

II INTERNATIONAL WORKSHOP: MANAGEMENT, INNOVATION AND ASSESSMENT OF HEALTH TECHNOLOGIES IN MEDICAL DEVICES

Léria Rosane Holsbach

PhD and post-doctorate in engineering with an emphasis on ergonomics, master's degree in Biomedical Engineering, specialization in clinical engineering and degree in electronic engineering. He has national and international experience in Technologies in the area of Health and Commercial Aviation. She worked as coordinator of clinical and biomedical engineering at Santa Casa de Porto Alegre for 25 years, in the evaluation and management of technologies (project planning, incorporation, maintenance, deactivation and disposal) and Hospital Accreditation. Teacher and researcher. Lines of research: Clinical research, ATS, Ergonomics/Usability, economic engineering in medical equipment. Consultant and projects for the following institutions: Healthcare companies in the United States of America, Turkey and Germany, Ministry of Education (MEC); Ministry of Health (MS), Anvisa; Coordination for the Improvement of Higher Education Personnel (CAPES); National Bank for Economic and Social Development (BNDES); Studies and Projects Financier (FINEP); Federal Engineering Council (CONFEA); World Health Organization (WHO). Member of the Technovigilance Technical Chamber/ Anvisa and MCTI in the health 4.0 technical chamber. Vice President of Scientific Technical Development – Abeclin. Member of the Enedina Marques/Abeclin Women's Committee. Author of books and articles in the field of Engineering and health. Reviewer of international and national scientific journals. Outstanding award: Clinical Engineering Outstanding Teamwork Award. international federation for Medical and Biological Engineering - Clinical Engineering Division – IFMBE.

Eduardo Coura Assis

Bachelor's degree in Electrical/Electronic Engineering from the University of Uberaba, Degree in Health Technology from the Faculty of Technology of Sorocaba (FATEC) and also a Bachelor's degree in Hospital Administration from the União Educacional de Brasília (UNEB). Specialist in Clinical Engineering from the State University of Campinas (UNICAMP). Master in Public Health, with an emphasis on Policy and Management in Science, Technology and Innovation in Health from the National School of Public Health, Sergio Arouca, from the Oswaldo Cruz Foundation (ENSP-FIOCRUZ-RJ). Specialist in Health Economics from the Institute of Clinical and Health Effectiveness of Buenos Aires, Argentina (IECS). MBA in Economics and Health Technology Assessment from FIPE and FEA/USP and Specialist in Hospital Engineering and Maintenance from INBEC/UNIP. He currently works as a Clinical Engineer at the Administrative Headquarters of the Federal District Strategic Management Institute (IGESDF). He worked for 8 years at the Bioequipment Engineering and Maintenance Center of the Hospital das Clínicas of the Faculty of Medicine of Ribeirão Preto of the University of São Paulo, where he was Technical Responsible for the Clinical Engineering Center of the HC Emergency Unit. He worked at the Ministry of Health for 12 years in the Department of Science and Technology, Department of Health Economics and Development and the National Health Fund, where he organized and was one of the authors of the first and only methodological guideline for preparing HTA studies on equipment doctors and its validation with the da Vinci robotic system in prostatectomies at Hospitals de Excelência de SP and published in three languages, was also responsible for conducting the first mapping in 15 regions of Brazil from the perspective of medical equipment management through the QUALISUS REDE PROJECT, in addition to authoring the self-instructional course on Medical Equipment Management for SUS managers through the AVASUS platform. He also worked for 01 year during the Covid pandemic at EBSERH Headquarters, where he collaborated with emergency acquisitions and in equipping the Hospital of the Federal University of Amapá, recently integrated into EBSERH. He also works as a professor at UFMT in the Specialization course in ATS and also in the MBA in ATS and Health Economics at HAOC.

Speakers

II INTERNATIONAL WORKSHOP: MANAGEMENT, INNOVATION AND ASSESSMENT OF HEALTH TECHNOLOGIES IN MEDICAL DEVICES

Fernanda de Carvalho Vieira

Master in Management and Innovation in Health, from the Federal University of Rio Grande do Norte (2020). Specialist in Clinical Engineering from the University of Brasília (2011) and in Health Economics from the University of Goiás (2022). Graduated in Electrical Engineering from the Military Institute of Engineering (2007). She is currently a Clinical Engineer at the Brazilian Hospital Services Company (EBSERH / MEC), at the Juiz de Fora University Hospital.

Francisco Iran Cartaxo Barbosa

Mechanical engineer, Master in public health from FIOCRUZ with dissertation "Applications as medical devices: Is there a risk at your fingertips?", 23 years in the health area and 10 years in the area of health equipment regulation, being mainly responsible for the process that led the publication of RDC 657/2022 which provides for the regularization of software as a medical device. Specialist in Health Regulation and Surveillance - Equipment Technology Management - GQUIP/GGTPS/ANVISA.

Gilberto Sebastião Zunta

Graduated in Electrical Engineering (School of Engineering of Lins, 1993) with a postgraduate degree in Clinical Engineering (Unicamp, 1998), Hospital Administration and Health System (FGV, 2003, Occupational Safety Engineering (USP, 2009) and a degree in Engineering Civil (Unisa, 2024). Works as a Clinical Engineer in the Health Equipment Group (GES), of the São Paulo State Department of Health (SES).

Fábio Martins Corrêa

He has a degree in Production Engineering (2015) and a degree in Health Technology from the Faculty of Technology of Sorocaba (2010). Specialization in Clinical Engineering from the Albert Einstein Teaching and Research Institute. Specialization in Hospital Administration and Health Systems from Fundação Getúlio Vargas. He is currently Director of Clinical Engineering at the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo - HCFMUSP. He also works as Coordinator of the Health Technology Assessment Center – NATS-HCFMUSP. He teaches classes at Faculdade da Américas - FAM, in the undergraduate course in Biomedical Engineering in the disciplines of Clinical Engineering, Hospital Facilities, Medical Equipment, Diagnostic Equipment, Medical Imaging and Maintenance of Hospital Equipment. Coordinates the MBA in Clinical Engineering at HCX – HCFMUSP and teaches the discipline of Clinical Engineering Dimensioning and Structure. He works as an Engineering solutions consultant at the company Quality n' Health.

II INTERNATIONAL WORKSHOP: MANAGEMENT, INNOVATION AND ASSESSMENT OF HEALTH TECHNOLOGIES IN MEDICAL DEVICES

Vinícius Tadeu Ramires

He has a degree in Production Engineering (2021) and a degree in Health Technology from the Faculty of Technology of Sorocaba (2008). Specialization in Clinical Engineering from the State University of Campinas. Master's degree in Research and Development: Medical Biotechnology from Universidade Estadual Paulista Júlio de Mesquita Filho, UNESP Botucatu, Brazil. He is currently the Clinical Engineering Manager at the Hospital das Clínicas of the Faculty of Medicine of Botucatu - HCFMB. He taught classes at the Bauru Faculty of Technology, in the discipline of Construction of Medical-Hospital equipment and graduation work for the Biomedical Systems Technology course, and Integrated Management System classes alongside the Industrial Automation Technology course.

Wilker Edson Leite Beicker

He has a degree in Faculty of Technology - Sorocaba from the Faculty of Technology - Sorocaba (2003), a degree in Administration from Universidade Paulista (2009), a professional master's degree in MBA - Executive in Health from Fundação Getúlio Vargas (2012) and further training in Public Management from Faculty of Economics, Administration and Accounting of Ribeirão - USP (SP) (2008) . He has experience in the Administration area.

Gustavo Meirelles

Radiologist, with medical residency, specialization and doctorate in thoracic radiology at Escola Paulista de Medicina - Universidade Federal de São Paulo, where he worked for many years as an affiliated professor and supervisor of resident doctors. Post-doctorate in PET/CT at Memorial Sloan-Kettering Cancer Center (New York), specialization in thoracic radiology at the University of British Columbia (Vancouver) and MBA in Business Management at Fundação Getúlio Vargas in São Paulo. Founder of the Community Innovation in Health, which has more than 4000 participants interested in the topic, and of Saúde4x, an initiative focused on education and consultancy in the area of innovation and digital transformation of health. He worked for almost 20 years at Grupo Fleury, as a radiologist and medical manager of radiology, strategy and innovation. He served as medical director and vice-president of Alliança Saúde and CEO of iDr - Crédito Diagnóstica Remota, a company focused on innovation, technology and digital transformation in the healthcare sector, where I am currently president of the board of directors. He gave conferences at medical and innovation events in 12 countries, having published more than 100 scientific articles in indexed journals, 50 book chapters and more than 200 articles at events. He supervised undergraduate and postgraduate theses and is a reviewer of scientific journals in the areas of medicine and innovation. He is a member of the Agfa Global Radiology Advisory Board and the Boehringer-Ingelheim Scientific Board. He founded Ambra Saúde, a startup focused on managing and storing medical images in the cloud, and is a partner and mentor of other startups in the sector, such as Kuri Saúde, Munai, Neuralmed, Salubrum and OniDoc. I am an advisor to the NGO Zoé and a columnist for MIT Sloan Management Review Brazil and The Yuan.

II INTERNATIONAL WORKSHOP: MANAGEMENT, INNOVATION AND ASSESSMENT OF HEALTH TECHNOLOGIES IN MEDICAL DEVICES

Evelinda Marramon Trindade

Evelinda Trindade, has a PhD in "Assessment and Incorporation of New Technologies in Services of the Brazilian Health System" from the Department of Preventive Medicine of the Faculty of Medicine of the University of São Paulo, FMUSP (2006) and a Master's degree in Microbiology and Immunology - University of Montreal (1986) postgraduate degree in Medicine - Federal University of Santa Maria (1976). Currently, she is a researcher at the Health Technology Assessment Network of the São Paulo Science, Technology and Innovation Coordination Network of the São Paulo State Department of Health - REPATS/SES-SP. ET is also a researcher at the Health Technology Assessment Center at the Hospital das Clínicas of the Faculty of Medicine of the University of São Paulo, HCFMUSP. Both ATS organizations are members and as representatives, in the Brazilian Health Technology Assessment Network, REBRATS, in the Department of Management and Incorporation of Technologies and Innovation in Health - DGITIS, of the Ministry of Health. He is currently a Technology Assessment evaluator of Health at the Superintendence of Hospital das Clínicas - HCFMUSP and volunteer ATS consultant for the Brazilian Ministry of Health, particularly for the National Health Surveillance Agency, Directorate of Surveillance in Technovigilance, Medicines and Inspection; as well as the National Commission for the Incorporation of Health Technologies into the Brazilian Public Health System - Conitec/SUS - and DGITS/MS. ET is passionate about transforming healthcare through innovative processes and technological advances. ET is experienced in formal and regulatory HTA from early Canadian projects, the Council for Health Technology Assessment - CETS, the Canadian Coordinating Office for Health Technology Assessment - CCOHTA (now the Canadian Drugs and Health Technologies Agency - CADTH) and Health Canada, which she has participated in since the 80s and 90s. Once back in her home country - Brazil, in 1999, at the National Health Surveillance Agency - ANVISA, she developed and led new ATS projects, such as the Surveillance of the Medical Devices Market - Technovigilância / ANVISA and the National Network of Surveillance Hospitals - Rede Sentinela / ANVISA. Working with the Brazilian Ministry of Health, since the year 2000, he designed and promoted HTA projects, such as the importance of the Brazilian Health Technology Assessment Network, REBRATS / DECIT-MS and the National Commission for the Incorporation of Health Technologies for the Brazilian Public Health System - Conitec / SUS, you can testify now. The latest projects have mobilized stakeholders from Brazil and other countries, where ET is involved to promote the decentralization of ATS, with the aim of increasing scientific production, penetration and training, for example, Rede Paulista - REPATS / SES-SP , amid other Brazilian states where she is actively teaching ATS and tutoring projects. Together, experience and scientific production, in relation to results research and economic evaluations, have currently made it possible to incorporate and finance new medicines, devices and medical procedures in the National SUS List in Brazil. With the same objectives, ET is currently involved in several ongoing and longitudinal research, seeking real-life results and economic assessments on medical and healthcare disciplines, promoting the development and analysis of large databases for the transformation of health care. health. The organization of regular annual REBRATS and REPATS-SES/SP events on larger scales has, lately, materialized the initial seeds of the dialogue necessary for the decentralization of ATS between researchers and managers in our jurisdictions.

II INTERNATIONAL WORKSHOP: MANAGEMENT, INNOVATION AND ASSESSMENT OF HEALTH TECHNOLOGIES IN MEDICAL DEVICES

Fotini Santos Toscas

Full member of the Products and Procedures Committee of the National Commission for the Incorporation of Technologies into the SUS (Conitec). Public Servant in the Scientific Research Career at the Center for Analysis and Assessment of Health Technologies (NAPATS). Guest expert at Anvisa's Technovigilance Technical Chamber. Guest expert at the Subcommittee on Products and Procedures of the Ministry of Health. Content teacher for the course Challenges for Technovigilance in the context of the development and use of innovative medical devices at Anvisa. Content writer for ATS Training Workshops on medical devices. Specialist Researcher in the OPAS Project: Study of the value chain in medical devices for Latin America. Associate researcher at the Laboratory of Teaching, Research and Innovation in Surgery at the Hospital de Clínicas of the Faculty of Medicine of the University of São Paulo (LEPIC/HCFMUSP). Teacher of the Health Technology Assessment discipline of the specialization course in Public Health SES/SP. Member of the Clinical Research Ethics Committee of the Institute of Health. From 2010 to 2020, she worked as a technical consultant at the Ministry of Health. Experience in technical analysis of investment project proposals in Research, Development and Innovation (PDI) in medical devices. Participation in the preparation, monitoring and evaluation of national notices to promote development and innovation in the field of medical devices. Participation in sectoral technical evaluations and studies of medical devices. Support in carrying out post-market and post-incorporation studies of medical-assistance equipment. Survey and exploratory research in the Ministry of Health's computerized systems to map the supply of medical care equipment. Participation in the dynamics of studying medical devices throughout the technological life cycle. She worked as an advisor to the Management of the Health Industrial Complex Department (DECIIS - SCTIE), directly advising on skills for formulating programs and actions to induce technological development, technology transfer, production and innovation in strategic inputs. Participated in the execution actions of the SUS Radiotherapy Expansion Plan, the Program to Promote the Development of the Industrial Health Complex (PROCIS), in the Partnerships for Productive Development (PDP) and in the preparation of a list of strategic products, within the scope of devices doctors. Participated in the creation and updating of RENEM - National List of Equipment and permanent materials financeable by the SUS regarding permitted and unacceptable configuration, specification and suggested price, nomenclature, applicability, definition, classification, synonyms, breakdowns by different technologies and pricing. Participated in the development and application of routines for analyzing the incorporation of new technologies and disincorporation of medical-hospital support equipment and infrastructure in RENEM. Worked on the implementation of SIGEM routines - Equipment Management System and permanent materials financeable by the SUS. Participated in activities for the preparation, monitoring of marketing research, research in specialized technical bibliography to support analysis of proposals from the Ministry of Health. Participated in the implementation and institutionalization of the Technical Cooperation Program (PROCOT) of the Ministry of Health, for medical and hospital technological updating.

Moderadores

II INTERNATIONAL WORKSHOP: MANAGEMENT, INNOVATION AND ASSESSMENT OF HEALTH TECHNOLOGIES IN MEDICAL DEVICES

Murilo Contó

25 years of experience in the area of health technologies, with an emphasis on medical devices and equipment, working with industry, hospitals and the federal government. Activities related to Health Technology Assessment (ATS) and Health Economics to promote rational access to technologies and activities related to Health Technology Management and Clinical Engineering. Elected member of the Board of IFMBE-HTAD (International Federation of Medical and Biological Engineering - Health Technology Assessment Division). Current Health Policy Manager at Boston Scientific do Brasil, responsible for the areas of Clinical Research, Health Economics and Government Relations. He served as National Consultant in Management and HTA for PAHO/WHO - Pan American Health Organization/World Health Organization; Ad-hoc INMETRO consultant as a specialist in electromedical equipment for audits of Product Certification Bodies; Consultant between 2012 and 2015 at CONITEC - National Commission for the Incorporation of Technologies into the SUS; and Manager of the division of equipment investment projects at the Ministry of Health between 2009 and 2012. He was responsible for the conception and creation of RENEM - National List of Equipment and Materials for the SUS; PROCOT - Program for Capturing Technical and Economic Information, and SIGEM - Information and Management System for Financial Equipment for the SUS. Graduated in Health Technology (FATEC Sorocaba, 1995), with postgraduate degrees in Hospital Administration (Centro Universitário São Camilo, 1997), Clinical Engineering (UNICAMP, 2000); MBA in Health Management (Fundação Getúlio Vargas, 2012); and Master's in Health Technology Assessment (National Institute of Cardiology, 2019).

Luís Gustavo Modelli de Andrade

Graduated in Medicine from Universidade Estadual Paulista Júlio de Mesquita Filho (2001), Medical Residency in Nephrology (UNESP - 2004), Master's and Doctorate in Pathophysiology in Clinical Medicine with area of expertise in Nephrology (UNESP 2007/2011). Specialization Course in Health Management from the Universidade Estadual Paulista (Latu sensu) in 2012. He currently works as a Nephrologist hired by HC Unesp since 2004 and current coordinator of kidney transplantation at the Faculty of Medicine of Botucatu since January 2015. Coordinator of the Health Management Program Solid Organ Transplants at HC UNESP since September 2017. He was a preceptor for the Medical Residency in Nephrology (2011/2015). Member of the Rare Diseases Committee (COMDORA) of the Brazilian Society of Nephrology since 2019. In recent years, he has been the Principal Investigator of artificial intelligence projects applied to health and transplants. Current coordinator of the HCFMB Health Data Sciences and Predictive Analysis Laboratory (LabData) since October 2021. Clinical study investigator (PI) in Rare diseases (Current - phase II/III for treatment of C3 Glomerulonephritis - Noble Study and phase III of crovalimab for the treatment of Atypical Hemolytic Uremic Syndrome).

Objective:

This workshop will address current topics on the management, innovation, and assessment of health technologies (HTA) in medical devices. Guest speakers are renowned professors and researchers in the medical device field.

Target Population:

Students (undergraduate and postgraduate courses in all health categories), residents (medical and multi-professional area), teachers, researchers, Members of Health Technology Assessment Centers, and health workers in general, especially in the areas of clinical engineering, biomedicine, and medical physics.

Services:

Simultaneous translation, online transmission of panels, space for stands, welcome cocktail, special platform for national and international registration and certificate after the event.

Registrations:

Registration and other information on the website
(Link coming soon)

Schedule | 10.25.2024 - Friday

8 -8:30 am

Registrations / Delivery of Materials and Phone for Translation

8:30 - 10 am

Panel Discussion 1 - General Aspects of Medical Devices, HTA, and Management Worldwide

Speakers:
→ **To confirm**
→ **To confirm**

Moderator:
→ **Evelinda Marramon Trindade**

10 - 10:20 am ***Coffee Break***

10:20 - 12:20pm

Panel Discussion 2 - Clinical Evidence Criteria for Medical Devices

Speakers:
→ **Debjani Mueller**
→ **Eduardo Coura Assis**
→ **Léria Rosane Hoslbach**

Moderator:
→ **Murilo Contó**

12:20 - 14 pm ***Reserved Lunch Time***

14 - 16 pm

Panel Discussion 3 - AI and Decision Support Systems: Ethics and Regulation, Software as a Medical Device

Speakers:
→ **Ernesto Iadanza**
→ **Gustavo Meirelles**
→ **Francisco Iran Cartaxo**

Moderator:
→ **Luis Gustavo Modelli de Andrade**

16 - 16:20 pm ***Coffee Break***

16:20 - 18:20 pm

Panel Discussion 4 - Participant's Inputs and Suggestions on the Practices in their Settings

Speakers:
→ **Vinicius Ramiris**
→ **Wilker Edsson Leite Beicker**
→ **Gilberto Zunta**
→ **Fernanda Vieira**

Moderator:
→ **Fotini Santos Tosca**

18:20 - 21 pm ***Cocktail for Speakers, Sponsors, Authorities and Participants***

Brasilia Standard Time
Time Zone in: Brasília, DF (GMT-3)

Schedule | 10.26.2024 - Saturday

8 - 10 am

CASE 1 - Local Experience

→ Fábio Martins Corrêa - NATS HCFMUSP

CASE 2 - International Experience

→ To Confirm

CASE 3 - IPEN - Nuclear and Energy Research Institute

→ To Confirm

10 - 10:20 am *Coffee Break*

10:20 - 12:20 pm

CASE 4 - Industry Experience - MINDRAY

→ To Confirm

CASE 5 - Industry Experience - ASTRAZENECA

→ To Confirm

CASE 6 - Industry Experience - SOLVENTUM

→ To Confirm

CASE 7 - Industry Experience - BOSTON SCIENTIFIC

→ To Confirm

Brasilia Standard Time
Time Zone in: Brasília, DF (GMT-3)

Schedule | 10.26.2024 - Saturday

14 - 17 pm

SHORT COURSE 1
Key Concepts About HTA Practice and Medical Devices

Coordinators:

→ **Fotini Santos Toscas**

→ **Evelinda Marramon Trindade**

SHORT COURSE 2
Main Concepts About the Practice of Artificial Intelligence as an Innovation in Health

Coordinator:

→ **Luis Gustavo Modelli de Andrade**

***IN-PERSON SHORT COURSE WITH LIMITED PLACES**

Brasilia Standard Time
Time Zone in: Brasília, DF (GMT-3)