



Danielle Nusimovici-Avadis, MD

Medical Director

Dr. Nusimovici-Avadis brings over 8 years of experience in the medical device development industry, including her extensive knowledge in clinical applications of new technologies. Her competence in regulatory and clinical affairs led to several successful clinical trials and regulatory submissions in Europe and in the US. She is a leading actor in translating new products from the R&D stage to the medical market. Her trinational thorough background (Israel, USA, France) in the medical device field allows her to lead projects in the new frontiers of that field. She was one of the first to join PVT (Start-up in the field of percutaneous heart valve – PVT Merged with Edwards Life science in 2004). She has worked as Medical Director for companies such as MediGuid, TrigMedical and FD Cardio. In her past professional career, she acquired experience in Research & Development of medical devices. Specifically, she was involved and published on a trans-catheter heart valve used in aortic heart valve replacement procedure, tracking and navigation system in terms of device components, delivery systems, catheters and imaging.

EXPERIENCE:

Medical Director, Emergo UK (formerly Mediqol Limited)

Medical & Clinical Director, TrigMedical, Ltd.

Company in the field of Obstetrics

Medical & Clinical Director, MediGuide, Ltd.

Company in the field of Interventional cardiology and navigation. Merged with St. Jude in 2008

Medical & Clinical Director, FD Cardio, Ltd.

Catheter company in the field of Interventional cardiology

Manager, Clinical Affairs, Percutaneous valve technologies Ltd. (P.V.T)

Merged with Edwards Lifesciences in 2004

Preclinical activities:

- Direct Cooperation with R&D team, and participation with R&D work
- Direct Cooperation with Medical Staff
- Conduct, elaboration and supervision of Feasibility Animal Studies
- Conduct, elaboration and supervision of Pre-clinical, non -laboratory studies
- Conduct, elaboration and supervision In vitro studies: Biocompatibility
- Elaboration of Histopathology studies



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Clinical activities

- Direct cooperation with Doctors.
- Responsible for managing team members located in different countries
- Development, implementation & execution of study protocols for clinical trials in Europe, North America and Brazil.
- Development of clinical trial strategies and investigation plans (protocol, case report forms, consents, instructions for use, hospital/pharmacy contracts, etc.)
- Familiar with European, FDA and ICH GCP guidelines
- Coordination of all site activities from trial/site set-up to closure (i.e., site selection, IRB approvals, routine monitoring/supervision, data management/locks, etc.) for applicable studies.
- Management & coordination of daily trial project management and data monitoring activities, including activities of clinical research organizations supporting studies,
- Communication with clinical sites, other Clinical Research staff, Scientific Committees/DSMBs (as permitted), & CROs to resolve problems & monitor/encourage enrollment.
- Organization/conducting clinical site monitoring visits as required. Coordinate/ conduct analysis of clinical data and disseminate clinical results to other departments &
- Provision of feedback to/from sites regarding improvements to technology/procedures.
- Participation in design review meetings and attending scientific meetings/industry conferences.
- Monitoring/CRA
- Familiar with EDC system (e.g. KIKA)

Regulatory activities

- Regulatory filings: US FDA 510(K) and PMA submissions. Europe and South America (AFSSAPS-France; Italy; Brazil)
- In depth knowledge of the regulatory requirements for Class I, IIa, IIb and III medical device products

Quality assurance

- Responsible for building a Quality Assurance (QA) system in order to obtain ISO Medical Certification



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AREAS OF EXPERTISE:

- Heart valves
- Interventional cardiology
- Navigation
- Obstetrics
- Data management support
- Extensive board level experience in start-ups, in the field of medical device
- Liaising between physicians and R&D team.
- Pre-clinical studies (biocompatibility- in vitro- animal and histopathology studies)
- Development, implementation & execution of study protocols for clinical trials in Europe, North America and Brazil
- Development of clinical trial strategies and investigation plans (protocol, case report forms, consents, instructions for use, etc.)
- Regulatory filings (PMAs- 510(K)s)
- QA requirements

EDUCATION:

- European License to practice medicine, Louis Pasteur University, Faculty of Medicine, Strasbourg, France - 1998
- Post-graduate diploma in pediatrics. Louis Pasteur University, Faculty of Medicine, Strasbourg, France - 1998
- M.D Thesis, “Summa cum Laude”, (Effects of vibration on patients during transportation Louis Pasteur University, Faculty of Medicine, Strasbourg, France - 2000
- Israeli Medical License - 2001
- CRA (Clinical Research Associate) Certification- Bio-log, Rehovot, ISRAEL - 2002

AFFILIATIONS

- Member of “ Ordre des Médecins,” France - 2000

LANGUAGE SKILLS

- French - Mother tongue
- English - Mother tongue
- Hebrew - Fluent
- Italian - Elementary knowledge



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PUBLICATIONS:

- Luchner, A. Jeron1, D. Nusimovici-Avadis, et al. "First in Man Experience with the Magnetic Medical Positioning System (MPS) for Intra-Coronary Navigation" Clin Res Cardiol 98, Suppl 1, April 2009
- Moshe Y Flugelman, Avinoam Shiran, Danielle Nusimovici-Avadis et al" Medical Positioning System: a Technical Report". EuroIntervention. Euro PCR 2008
- Cribier ; Helene Eltchaninoff; Danielle Nusimovici et al. "Early Experience With Percutaneous Transcatheter Implantation of Heart Valve Prosthesis for the treatment of end-stage inoperable patients with Calcific Aortic Stenosis" JACC Vol 43, No4 2004:698-703.
- Cribier ; Helene Eltchaninoff; Danielle Nusimovici et al. « Early Experience With Percutaneous Aortic Valve implantation in Patients with Severe non-Operable Aortic Stenosis" Abstract ACC(control/Tracking number 04-A-293635-ACC)
- Helene Eltchaninoff; A. Cribier ; Danielle Nusimovici et al. " Percutaneous Implantation of a new Prosthetic heart valve in the descending Aorta in sheep: Results at 6 weeks in a model of sever Aortic Insufficiency" American College of Cardiology. (control/Tracking number 04-A-293424-ACC)
- Helene Eltchaninoff; A. Cribier ; Danielle Nusimovici et al. "Five month study of a percutaneous heart valves in the systemic circulation of sheep using a novel model of aortic insufficiency – EuroInterv,2006;1:438-444