

# Curriculum Vitae



## Personal information

First name(s) / Surname(s) **Roșu Șerban Marius**

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Nationality Romanian

Date of birth 21<sup>st</sup> of February 1974

Gender Male

## Desired employment / Occupational field

**Project Manager**

### Work experience University Career

Dates 2017-Present

Occupation or position held Professor Associate

Main activities and responsibilities Teaching the Course of Oral and Cranio-Maxillo-Facial Surgery

Name and address of employer [Victor Babeș University of Medicine and Pharmacy of Timișoara](#), Faculty of Dental Medicine, Department of Oral and Cranio-Maxillo-Facial Surgery

Type of business or sector Higher education

Dates 2005-2017

Occupation or position held Professor Assistant

Main activities and responsibilities Teaching practical activities of Oral and Cranio-Maxillo-Facial Surgery to students

Name and address of employer Victor Babeș University of Medicine and Pharmacy of Timișoara, Faculty of Dental Medicine, Department of Oral and Cranio-Maxillo-Facial Surgery

Type of business or sector Higher education

### Work experience Clinical trials

Dates 2012-present

Occupation or position held Scientific director, partner (owner)

Main activities and responsibilities Clinical trial design, medical writing (protocols, final reports, scientific articles), monitoring (CRA activities)

Name and address of employer [Opera CRO Romania, Cozia 10 str, 300209, Timisoara](#)

Dates 2014-2016

Occupation or position held **Project manager, medical writer in following trials (below)**

Main activities and responsibilities Overall coordination and management of the clinical trial from startup to closeout  
Direction of the technical, protocol-specific and operational aspects of assigned trials  
Collaboration with major functional areas to identify and evaluate fundamental issues on the project, interpret data, make good business decisions and ensure the implementation of timely solutions  
Assist in the planning and execution of clinical trials while adhering to budget, scope and timelines  
CRO & vendor selection and oversight to ensure patient safety, adherence to the contract, protocol and appropriate safety regulations and data integrity. Serve as primary contact and resource for LCRA, CRO and vendor personnel. Work with Clinical Trial Managers, Data Management, Clinical Trial Assistant and Document Control Specialist to create and manage study related documents.  
Lead planning and communication with cross-functional teams to ensure proper execution and conduction of the trial.  
Track and report on the progress of assigned clinical trials including budget and timelines.  
Preparation, oversight and review of study related documents including contracts, protocols, informed consent forms, vendor and site budgets, annual reports, etc.  
Participate in the preparation, review, updating and training of SOPs, ensure compliance to SOPs.  
Co-monitor with CRO's Monitors to evaluate and ensure quality of CRO Monitoring Team. Ensure that studies are conducted in accordance with the protocol, GCP / ICH guidelines, FDA regulations and departmental SOPs.  
Organize (or assists with organizing) and participates in meetings – i.e. Study Team Meetings, Investigator Meetings, Monitors' workshops, and CRO Training.  
Accountability for ensuring all project deliverables meet customers' expectations as well as legal standards. Accurate forecasts

**Sponsor:** [SIFI MedTech Italy](#)

**Condition:** Cataract

**Title:** Retrospective observational trial on the visual performances of a Progressive Multifocal intraocular lens with extended depth of focus

**NCT:** [02740010](#)

**Study Type:** Retrospective trial

**Study Design:** Retrospective observational trial

**IMP:** Medical device

**No. of clinical sites/countrie(s):** 5/Italy

- [Prof. Dr. Giovanni Alessio](#) ~ [U.O. Oftalmologia Universitaria, Bari](#)
- [Dr. Giacomo Savini MD](#) ~ [I.R.C.C.S. Fondazione G.B. Bietti, Roma](#)
- [Dr. Scipione Rossi](#) ~ [UOC Oculistica Ospedale San Carlo di Nancy, Roma](#)
- Dr. Claudio Carbonara ~ [Clinica Villa Valeria, Roma](#)
- Dr. Claudio Carbonara ~ [Clinica Nuova Itor, Roma](#)

**Sponsor:** [SIFI MedTech Italy](#)

**Condition:** Cataract

**Title:** An open label, non-comparative study to assess the visual performances and safety of a progressive multifocal intraocular lens with extendeddepth of focus

**NCT:** [02838004](#)

**Study Phase:** III

**Study Type:** Interventional

**Study Design:** open label, non-comparative trial

**IMP:** Medical device

**No. of clinical sites/countrie(s):** 1/ Germany, 2/Italy, 2/Romania

- [Prof. Dr. med. Gerd U. Auffarth](#) ~ [Ruprecht -Karls-Universitäts-Augenklinik, Heidelberg \(Germany\)](#)
- Prof. Dr. Daniele Tognetto ~ [Unità Clinica Operativa Clinica Oculistica, Ospedale Maggiore, Trieste \(Italy\)](#)
- [Dr. Paolo Bordin](#) ~ [ULSS 9 ScaligeraASL 9, Verona \(Italy\)](#)
- [Dr. Ozana Moraru](#) ~ [Centrul Oftalmologic Oculus, Bucuresti \(Romania\)](#)
- [Prof. Dr. Mihnea Munteanu](#) ~ [Centrul Oftalmologic Prof. Dr. MUNTEANU, Timisoara \(Romania\)](#)

**Sponsor:** [Effik Italia SpA](#)

**Condition:** Recurrent Bacterial Vaginosis

**Title:** A multicenter, open label, non-comparative, 3 months study to assess the performance and safety of the new medical device Polybactum® in reducing the frequency of Recurrent Bacterial Vaginosis

**NCT:** [02863536](#)

**Study Phase:** III

**Study Type:** Interventional

**Study Design:** multicenter, open label, non-comparative trial

**IMP:** Medical device

**No. of clinical sites/countrie(s):** 3/Italy, 3/Romania

- [Dr. Filippo Murina](#) ~ [Ospedale Vittore Buzzi, Milano \(Italy\)](#)
- [Prof. Carmine Carriero](#) ~ [Policlinico Universita' di Bari \(Italy\)](#)
- [Dr. Paolo Inghirami](#) ~ [AIED – Via Gorizia, Roma \(Italy\)](#)
- [Dr. Ciprian Crisan](#) ~ [Clinica Medicala Dr. Crisan Ciprian, Timisoara \(Romania\)](#)
- [Dr. Marius Biris](#) ~ PFA Biris Marius Medic Independent, Timisoara (Romania)
- Dr. Daniela Sirbu ~ Clinica Medicala Dr. Sirbu Daniela, Timisoara (Romania)

**Sponsor:** [Mdm SpA Italy](#)

**Condition:** Acute low back pain

**Title:** A phase III, multicenter, randomized, parallel groups study to assess the efficacy and safety of 0,5 mg TIZASPRAY® administred intranasally versus SIRDALUD® 2 mg tablets in patients with acute low back pain

**NCT:** [02934061](#)

**Study Phase:** III

**Study Type:** Interventional

**Study Design:** multicenter, randomized, parallel groups trial

**IMP:** Drug

**No. of clinical sites/countrie(s):** 3/Italy, 5/Romania

- Delia Cinteza MD, PhD ~ [Institutul National de Recuperare, Medicina Fizica si Balneoclimatologie – Clinica Recuperare Neurologica IV – Bucuresti \(Romania\)](#)
- Augustin Dima MD ~ [Institutul National de Recuperare, Medicina Fizica si Balneoclimatologie – Clinica I – Bucuresti \(Romania\)](#)
- Mihaela Cristina China MD ~ [Medical Center for Diagnosis and Treatment Dr. Ovidiu Cristian Chiriac, Bucuresti \(Romania\)](#)
- Prof. Assoc. Doina Rosu MD PhD ~ SCM Gados, Timisoara, Romania
- Andor Bogdan ~ Medicali's, Timisoara, Romania

**Sponsor:** [Mdm SpA Italy](#)

**Condition:** Dyslipidemia

**Title:** A pilot, open label, non-comparative study to assess the efficacy and safety of the new Food Supplement FaseMETS® in the management of dyslipidemia

**NCT:** [02912325](#)

**Study Phase:** III

**Study Type:** Interventional

**Study Design:** Pilot, open label, non-comparative trial

**IMP:** Food Supplement

**No. of clinical sites/countrie(s):** 2/Romania

Dr. Adrian Enache ~ [SCM Dr. ROSU, Timisoara \(Romania\)](#)

Prof. Assoc. Gabriela Doina Negrisanu ~ [Centrul Medical Dr. Negrisanu Timisoara \(Romania\)](#)

**Sponsor:** [Mdm SpA Italy](#)

**Condition:** Acute low back pain

**Title:** A phase II, multicenter, randomized, parallel groups study to assess the efficacy and safety of two dose levels (0,5 mg and 1 mg) TIZASPRAY administered intranasally versus SIRDALUD® 4 mg, in patients with acute low back pain

**Study Phase:** II

**Study Type:** Interventional

**Study Design:** multicenter, randomized, parallel groups trial

**IMP:** Drug

**No. of clinical sites/country(ies):** 3/Romania

- Prof. Assoc. Doina Rosu MD PhD ~ SCM GADOS, Timisoara (Romania)
- Prof. Dr. Dan Nemes MD ~ [Cardinal Med Timisoara \(Romania\)](#)
- Prof. Assoc. Dr. Sanda Deme MD, PhD ~ [Spitalul Clinic de Urgenta Arad \(Romania\)](#)

**Sponsor:** [Iuppa Industriale Italy](#)

**Condition:** Pediatric functional constipation

**Title:** An Open label, non-comparative pilot study to assess the efficacy and safety of the Food Supplement Physiomanna® Baby in pediatric patients with a history of functional constipation

**NCT:** [02732743](#)

**Study Phase:** IV

**Study Type:** Interventional

**Study Design:** Open Label, noncomparative, pilot trial.

**IMP:** Food Supplement

**No. of clinical sites/country(ies):** 3/Romania

- [Prof. Assoc. Dr. Mihai Gafencu MD, PhD](#) ~ [Emergency Children Hospital "Luis Turcanu", Timisoara](#)
- Prof. Assoc. Dr. Rosu Serban MD, PhD ~ SCM GADOS, Timisoara
- Dr. Herteg Dorina MD ~ Cabinet Medical Dr. Herteg Dorina Timisoara

**Sponsor:** [SIFI MedTech Italy](#)

**Condition:** Cataract

**Title:** A multicentre, controlled, randomised, single-blind, two-armed, non-inferiority trial evaluating the visual performance, quality of vision and subjective outcomes with a 6 months follow up after bilateral implantation of Mini Well ready®, a progressive extended depth of focus intraocular lens, or Finevision®, a trifocal intraocular lens, in patients with cataract surgery.

**NCT:** [03060954](#)

**Study Phase:** III

**Study Type:** Interventional

**Study Design:** A multicentre, controlled, randomised, single-blind, two-armed, non-inferiority trial

**IMP:** Medical device

**No. of clinical sites/country(ies):** 2/France

Prof. Béatrice Cochener ~ [Ophtalmologie Hôpital Morvan, Brest](#)

[Dr. Pascal Rozot MD](#) ~ [Clinique Juge, Marseille](#)

**Sponsor:** [Bioplax Limited](#)

**Condition:** Infant teething

**Title:** Performance and tolerability of a new medical device protective gel for the symptomatic relieve of pain due to teething in infants: a randomized , open label, parallel-groups, multicenter study versus Dentinox®- Gel N (Tincture of Chamomile, Lidocaine Hydrochloride, Polidicanol 600).

**Study Type:** Interventional

**Study Design:** a randomized , open label, parallel-groups, multicenter trial

**IMP:** Medical device

**No. of clinical sites/country(ies):** 2/Romania

- Assoc. Dr. Serban Rosu, MD, PhD ~ [SCM DR.ROSU, Timisoara](#)
- [Prof. Assoc. Dr. Mihai Gafencu, MD, PhD](#) ~ [Emergency Children Hospital "Luis Turcanu", Timisoara](#)

## Work experience Researcher

Dates	2011-2014
Occupation or position held	<b>Principal Investigator, Coordinator of the trial</b>
Main activities and responsibilities	<p>promptly respond to all requests for information or materials solicited by the authorities, including the timely submission of the research;</p> <p>ensure that adequate resources and facilities are available to carry out the proposed research study;</p> <p>ensure that all associates, colleagues, and other personnel assisting in the conduct of the research study are appropriately informed of (i) the study procedures; (ii) informed consent requirements; (iii) the potential adverse events associated with study participation and the steps to be taken to reduce potential risks; (iv) adverse event reporting requirements; and (v) data collection and record-keeping criteria;</p> <p>conduct the study in strict accordance with the current authorities-approved research protocol except where a change may be necessary to eliminate an apparent immediate hazard to a given human research subject;</p> <p>report promptly to the authorities any deviations from the currently approved research protocol;</p> <p>obtain prospectively and documenting informed consent</p> <p>report promptly to the authorities (and, if applicable, the sponsor) any internal or external adverse event that is considered to be 1) unexpected; 2) serious and 3) possibly or definitely related to the study;</p> <p>report promptly to the authorities any significant changes in the risk/benefit of study participation;</p> <p>ensure that, in the event a research subject experiences a significant adverse event, every reasonable effort is made to provide the subject with adequate care to correct or alleviate the consequences of the adverse event to the extent possible;</p> <p>ensure that conduct of the research study adheres to good clinical practice guidelines. ensure that all research investigators and coordinators have completed the good clinical practices training maintain adequate and accurate research subject records to reflect adherence to protocol specific requirements.</p>
Clinical trial	<p><b>Title:</b> A randomized, open, parallel-group multicenter study of efficacy and tolerability of a new medical device in gel formulation (Hyaluronic Acid 0.54%) versus Calgel® (Lidocaine 0.33% and Cetylpyridinium Chloride 0.10%) for the topical treatment of teething in infants</p> <p><b>NCT:</b><a href="https://clinicaltrials.gov/ct2/show/study/NCT02931357">02931357</a> (Clinicaltrials.gov)</p> <p><b>Study Type:</b> Interventional</p> <p><b>Study Design:</b> A randomized, open, parallel-group multicenter trial</p> <p><b>IMP:</b> Medical device</p> <p><b>No. of clinical sites/countrie(s):</b> 2/Romania</p> <ul style="list-style-type: none"><li>• <a href="#">Prof. Assoc. Dr. Mihai Gafencu MD, PhD</a> ~ <a href="#">Emergency Children Hospital "Luis Turcanu", Timisoara</a></li><li>• Prof. Assoc. Dr. Serban Rosu MD PhD. ~ <a href="#">SCM Dr. ROSU, Timisoara</a></li></ul>
Sponsor	<a href="#">Ricerfarma, Italy</a>
CRO	Latis srl, Italy
Dates	2003-2004
Occupation or position held	Researcher
Main activities and responsibilities	Clinical research (see above description)
Name and address of employer	Politehnica University of Timișoara, BCUM Project, Cod CNCSIS 33 Grant C.N.C.S.I.S., 2002-2004, subject 10, code 11, contract no. 33550 / 01.07.2003 BIOTECH Programme - subprogramme 6 : "Research on the dynamics of the jaw and the modelling of implants for the correction of its accidental fractures by means of surgical operations"
Type of business or sector	Research
Dates	2002
Occupation or position held	Researcher
Main activities and responsibilities	Clinical research (see above description)

Name and address of employer	Politehnica University of Timișoara Project type A on "Contributions to the improvement of the population's state of health by projecting prosthetic appliances, surgical toolkits and implant outfits for the remedy of the deflections on the skeleton", from the National Plan of Research, Development and Innovation. Grant P.N.C.D.I, BIOTECH Programme 2002-2005, contract no. 02-6-PA-346.
Type of business or sector	Research
Dates	2001
Occupation or position held	Researcher, co-investigator
Main activities and responsibilities	Clinical research (see above description)
Name and address of employer	Victor Babeș Medicine and Pharmacy University of Timișoara, Faculty of Dental Medicine, Department of Oral and Cranio-Maxillo-Facial Surgery International clinical research "Open Randomized Clinical Trial To Evaluate The Anti-Edema Activity Of Escin Vials vs Standard Steroid Therapy After Surgery for Jaw Fracture, ERASMUS (Edeven® Randomized vs Steroid Multicenter Study)" The research took place concomitantly in two countries : Italy and Romania
Type of business or sector	Research
Dates	2002
Occupation or position held	Researcher
Main activities and responsibilities	Clinical research, co-investigator (see above description)
Name and address of employer	Politehnica University of Timișoara Project BCUM, Code CNCSIS 33 "Centre for Modelling the Prosthetic Appliances and Surgical Operations on Human Skeleton CM-PICSU"
Type of business or sector	Research

## **Work experience    Medical Doctor**

Dates	2010-Present
Occupation or position held	Primary doctor in Oral and Cranio-Maxillo-Facial Surgery, Doctor in Medical Sciences
Main activities and responsibilities	Surgery
Name and address of employer	Municipal Emergency Clinical Hospital of Timișoara
Type of business or sector	Human Medicine
Dates	2005-2010
Occupation or position held	Specialist doctor in Oral and Cranio-Maxillo-Facial Surgery, Doctor in Medical Sciences
Main activities and responsibilities	Surgery
Name and address of employer	Municipal Emergency Clinical Hospital of Timișoara
Type of business or sector	Human Medicine
Dates	1998-2005
Occupation or position held	Resident doctor in Oral and Cranio-Maxillo-Facial Surgery
Main activities and responsibilities	Surgery
Name and address of employer	Municipal Emergency Clinical Hospital of Timișoara
Type of business or sector	Human Medicine
Dates	2000-present
Occupation or position held	Doctor stomatologist

Main activities and responsibilities Stomatology, Dental implantology  
Name and address of employer Medical clinic Doctor Roşu SCM  
Type of business or sector Human Medicine

## Education and training

Dates 2005-2010  
Title of qualification awarded **Primary medical doctor** – Highest medical position superior to specialist (Romania only)  
Principal subjects/occupational skills covered Specialist doctor in Oral and Cranio-Maxillo-Facial Surgery  
Name and type of organisation providing education and training Victor Babeş University of Medicine and Pharmacy of Timișoara, Faculty of Dental Medicine, Department of Oral and Cranio-Maxillo-Facial Surgery

Dates 2000-2006  
Title of qualification awarded **Doctorate (PhD)** Awarded “Cum Laude” - Medical Science  
Principal subjects/occupational skills covered Post Graduate  
Name and type of organisation providing education and training Victor Babeş University of Medicine and Pharmacy of Timișoara, Faculty of Dental Medicine, Department of Oral and Cranio-Maxillo-Facial Surgery

Dates 2000-2005  
Title of qualification awarded **Specialist medical doctor**  
Principal subjects/occupational skills covered Resident medical doctor of Oral and Cranio-Maxillo-Facial Surgery, post graduate  
Name and type of organisation providing education and training Victor Babeş University of Medicine and Pharmacy of Timișoara, Faculty of Dental Medicine, Department of Oral and Cranio-Maxillo-Facial Surgery

Dates 1998-2000  
Title of qualification awarded **Dentist**  
Principal subjects/occupational skills covered Junior medical doctor  
Name and type of organisation providing education and training Victor Babeş University of Medicine and Pharmacy of Timișoara, Faculty of Dental Medicine

Dates 2003  
Principal subjects/occupational skills covered Training Course in Clinical Research  
Name and type of organisation providing education and training J. Medical Books, Genova, Italy

Dates 2002  
Principal subjects/occupational skills covered Oral Implantology Course  
Name and type of organisation providing education and training Victor Babeş University of Medicine and Pharmacy of Timișoara, Faculty of Dental Medicine, Department of Oral and Cranio-Maxillo-Facial Surgery

Dates 1996-2002  
Title of qualification awarded **Medical doctor - general medicine**  
Name and type of organisation providing education and training Timișoara University of Medicine and Pharmacy, Faculty of Stomatology

Dates 1992-1998  
 Title of qualification awarded **Doctor stomatologist (Dentist)**  
 Name and type of organisation providing education and training Timișoara University of Medicine and Pharmacy, Faculty of Stomatology

Dates 1988-1992  
 Title of qualification awarded Junior programmer  
 Principal subjects/occupational skills covered Programming  
 Name and type of organisation providing education and training Grigore Moisil Highschool of Informatics

Dates 1980-1988  
 Name and type of organisation providing education and training Nikolau Lenau Highschool, German teaching school

### Personal skills and competences

Mother tongue(s) **Romanian**

Other language(s)

Self-assessment <i>European level (*)</i>	Understanding		Speaking		Writing
	Listening	Reading	Spoken interaction	Spoken production	
<b>English</b>	C2	C2	C2	C2	C2
<b>German</b>	C2	C2	C2	C2	C2
<b>French</b>	A2	A2	A1	A1	A1

(\*) [Common European Framework of Reference for Languages](#)

Social skills and competences Competence to speak extempore in front of a group of people as a consequence of the activity of teaching courses to the students

Organisational skills and competences Competence of organizing a private company (Manager of the Medical Clinic Doctor Roșu 2000-present)  
 Competence of conducting clinical researches

Computer skills and competences Very good skills of computer managing

Driving licence Holder of a driving licence for the B category

### Annexes

10.01.2017

Șerban Roșu