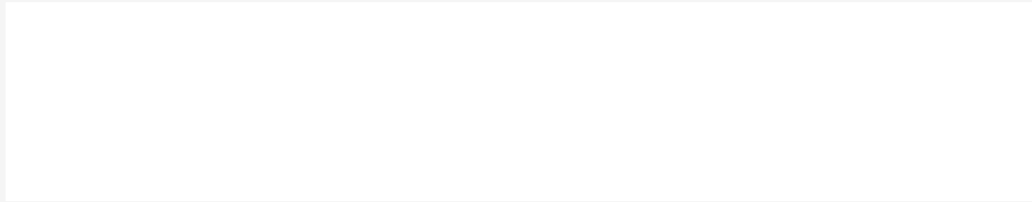




Mihai Ioan Manolache



● **EDUCATION AND TRAINING**

2017

IMMUNOLOGY & GENETICS – Harvard Medical School - USA

01/04/2012 – 23/11/2012

PG - CLINICAL TRIALS MANAGEMENT – "Carol Davila" University of Medicine & Pharmacy Bucharest

01/10/2014 – 15/06/2016

MASTER IN BIOSTATISTICS – Faculty of Mathematics & Informatics - University of Bucharest

01/10/2011 – 15/06/2015 "Spiru Haret" University Bucuresti

LICENSED IN LAW – Faculty of Law and Public Administration Bucharest

01/10/1999 – 15/06/2003 Pitesti State University

LICENSED IN ADMINISTRATIVE SCIENCES – Faculty of Economics and Administrative Sciences

15/09/1995 – 15/06/1999 Pitesti City

BACHELOR DEGREE – "Zinca Golescu" National College

● **WORK EXPERIENCE**

01/06/2016 – CURRENT – Lugano, Switzerland

PRESIDENT & CEO – CEBIS International SAGL

CEBIS International is a Global Swiss-Based Full Service Contract Research Organization (CRO).

CEBIS provides two major services—clinical research services and patient support programs. The clinical research services cover medical writing, regulatory affairs, monitoring, data management, biostatistics, and publishing, working closely with pharmaceutical, biotechnology, and medical devices companies. On the other hand, the patient support division is focused on medication adherence and technology-based interventions.

With well over three decades of experience in clinical research, the company's expertise and know-how together with utilizing standard validated procedures, and total quality management tools are offering clients accurate and on-time deliveries.

As CEBIS' CEO sets the policies and strategic direction for the company, both for the near term and for the foreseeable future. It is responsible to ensure the company follows its mission, policies and procedures that are in place, and is profitable.

Drives the team of executives to guide and oversee their departments and the managers who report to them, so they stay on track towards reaching their agreed upon goals. Regularly asks for verbal updates and formal reports so to know where each department and the company as a whole stands at all times. Mihai is the founder of CEBIS International.

Clinical Research - Patient Support - Business Process Outsourcing | Human health and social work activities |

www.cebis-int.com



2016 – CURRENT – Bucharest, Romania

CHAIRMAN – CRN - Clinical Research Network

CRN is an European Site Management Organization having an investigators network with more than 300 sites. CRN is conducting clinical research and providing support to pharmaceutical companies and CRO for the new medicine development.

Originally formed with a focus on gastroenterology and diabetes, CRN's research areas have extended to include Cardiovascular Diseases, Oncology, Orthopedic, Dermatology, Rheumatology, Gynecology, Urology, Neurology, Hematology. Over the years, the CRN has developed expertise in supporting epidemiology and population health research studies. Responsible for company's management activities.

Human health and social work activities | <https://www.clinicalresearch-network.com/>

2018 – CURRENT – Bucharest, Romania

GENERAL MANAGER – HMI - Health Media International

HMI - Health Media International offers quality Employment Agency services to place the right people with the right jobs. Whether you are looking to hire new staff we're happy to offer you our services. HMI offers full-service staffing in Healthcare and Pharmaceutical industry. HMI is an Authorized Agency by the Ministry of Labor. We are specialized in employment and outsourcing services for the medical and pharmaceutical industry.

Other service activities | www.healthmedia-int.com

10/2020 – CURRENT – Bucharest, Romania

GENERAL MANAGER – Aborg HealthCare

Aborg HealthCare is a specialty pharmaceutical consulting company providing services like: management, marketing, specialized services to pharmaceutical companies.

2015 – CURRENT – Bucharest, Romania

GENERAL MANAGER – CEBIS Medical Research

CEBIS Medical Research (CMR) is a specialized network of nurses, caregivers and doctors which provide support during patient support programs or clinical research services. CMR is working closely with more than 200 nurses, 100 caregivers and more than 8,000 MDs at the national level.

07/2016 – CURRENT – Bucharest, Romania

PRESIDENT & CEO – CEBIS International SRL

CEBIS International is a Global Swiss-Based Full Service Contract Research Organization (CRO).

CEBIS provides two major services—clinical research services and patient support programs. The clinical research services cover medical writing, regulatory affairs, monitoring, data management, biostatistics, and publishing, working closely with pharmaceutical, biotechnology, and medical devices companies. On the other hand, the patient support division is focused on medication adherence and technology-based interventions.

With well over three decades of experience in clinical research, the company's expertise and know-how together with utilizing standard validated procedures, and total quality management tools are offering clients accurate and on-time deliveries.

As CEBIS' CEO sets the policies and strategic direction for the company, both for the near term and for the foreseeable future. It is responsible to ensure the company follows its mission, policies and procedures that are in place, and is profitable. Drives the team of executives to guide and oversee their departments and the managers who report to them, so they stay on track towards reaching their agreed upon goals. Regularly asks for verbal updates and formal reports so to know where each department and the company as a whole stands at all times. Mihai is the founder of CEBIS International.

Human health and social work activities | www.cebis-int.com



● **LANGUAGE SKILLS**

Mother tongue(s): ROMANIAN

	UNDERSTANDING		SPEAKING		WRITING
	Listening	Reading	Spoken production	Spoken interaction	
ENGLISH	C2	C2	C2	C2	C2
FRENCH	B1	B1	A1	A1	B1
ITALIAN	B1	B1	A2	A2	B1
SPANISH	A1	A1	A1	A1	A1

Levels: A1 and A2: Basic user; B1 and B2: Independent user; C1 and C2: Proficient user

● **DIGITAL SKILLS**

Excellent knowlende of graphic software (Adobe Photoshop Adobe Indesign Adobe Illustrator) | Graphic editors Adobe Photoshop Corel Draw Studio 10 plus Photo Mechanic | Final Cut - Pro | LINUX UNIX MAC OSX WINDOWS | SPSS Statistical Tool | Modelling and preparation of data were done using SAS R Python Tableau Microsoft SQL Server | - Html css | Data Management and Data Analysis | Biostatistic | Medical Writing | Medical Devices | Clinical Research | Drug development | Research Methodologies | Clinical Trial | Project Management | Staff Management | Regulatory Affairs | Research Ethics | Research Proposal Initiating Research | Commercial Awareness | Pharmaceutical Marketing | Promotional Content Writing | Health Promotion Education

● **PUBLICATIONS**

Bioethics Approach of Biostatistics în Clinical Trials. Avoid The Use of Excessive of Inadequate Numbers of Research Subjects

http://www.josa.ro/docs/josa_2018_1/b_07_Manolache_239-246.pdf – 2018

Manolache, M., Cadar, E., Antonescu, D., et al (2018) Bioethics Approach of Biostatistics în Clinical Trials. Avoid The Use of Excessive of Inadequate Numbers of Research Subjects. Journal of Science and Arts. 1 239-246. http://www.josa.ro/docs/josa_2018_1/b_07_Manolache_239-246.pdf

Phenomenological and Mathematical Evaluation of Aberrant Values (Outliers) in Bioequivalence Studies

<http://www.scientificarray.org/jabp-v5a4/> – 2017

Manolache, M., C. Mircioiu, I. Mircioiu, I., et. Al (2017) Phenomenological and Mathematical Evaluation of Aberrant Values (Outliers) in Bioequivalence Studies. Journal of Applied Biopharmaceutics and Pharmacokinetics, 2017, 5, 19-25 <http://www.scientificarray.org/jabp-v5a4/>



New evidence on oral *L. plantarum* P17630 product in women with history of recurrent vulvovaginal candidiasis (RVVC): a randomized double-blind placebo-controlled study

<https://pubmed.ncbi.nlm.nih.gov/29364495/> – 2018

Vladareanu R, Mihu D, Mitran M, Mehedintu C, Boiangiu A, Manolache M, Vladareanu S. New evidence on oral *L. plantarum* P17630 product in women with history of recurrent vulvovaginal candidiasis (RVVC): a randomized double-blind placebo-controlled study. *Eur Rev Med Pharmacol Sci*. 2018 Jan;22(1):262-267. doi: 10.26355/eurrev_201801_14128. PMID: 29364495. <https://pubmed.ncbi.nlm.nih.gov/29364495/>

Effectiveness and safety profile of ipilimumab therapy in previously treated patients with unresectable or metastatic melanoma - the Romanian Patient Access Program

<https://pubmed.ncbi.nlm.nih.gov/29135115/> – 2017

Corneliu Jinga D, Ciuleanu T, Negru S, Aldea C, Gales L, Bacanu F, Oprean C, Manolache M, Zob D, Curescu S, Stanculeanu DL. Effectiveness and safety profile of ipilimumab therapy in previously treated patients with unresectable or metastatic melanoma - the Romanian Patient Access Program. *J BUON*. 2017 Sep-Oct;22(5):1287-1295. PMID: 29135115. <https://pubmed.ncbi.nlm.nih.gov/29135115/>

Cardiovascular Risk Assessment in the Adult (Aged 40-79 Years) Romanian Population

<https://pubmed.ncbi.nlm.nih.gov/31149262/> – 2018

5. Rosu MM, Popa SG, Mota E, Popa A, Manolache M, Guja C, Bala C, Mota C, Mota M. CARDIOVASCULAR RISK ASSESSMENT IN THE ADULT (AGED 40-79 YEARS) ROMANIAN POPULATION. *Acta Endocrinol (Buchar)*. 2018 Apr-Jun;14(2):227-234. doi: 10.4183/aeb.2018.227. PMID: 31149262; PMCID: PMC6516525. <https://pubmed.ncbi.nlm.nih.gov/31149262/>

Gelatin tannate versus other antidiarrheal medication in children with acute gastroenteritis: a retrospective, observational study

<https://pubmed.ncbi.nlm.nih.gov/30644329/> – 2019

Serban ED, Manolache M. Gelatin tannate versus other antidiarrheal medication in children with acute gastroenteritis: a retrospective, observational study. *J Comp Eff Res*. 2019 Feb;8(3):187-194. doi: 10.2217/ceer-2018-0082. Epub 2019 Jan 15. PMID: 30644329. <https://pubmed.ncbi.nlm.nih.gov/30644329/>

Efficacy and safety of APT198K for the treatment of infantile colic: a pilot study

<https://pubmed.ncbi.nlm.nih.gov/28114795/> – 2017

Vandenplas Y, Bacarea A, Marusteri M, Bacarea V, Constantin M, Manolache M. Efficacy and safety of APT198K for the treatment of infantile colic: a pilot study. *J Comp Eff Res*. 2017 Mar;6(2):137-144. doi: 10.2217/ceer-2016-0059. Epub 2017 Jan 24. PMID: 28114795. <https://pubmed.ncbi.nlm.nih.gov/28114795/>

Sources of outlier data in the bioanalytical and clinical part of a piroxicam bioequivalence study

<https://pubmed.ncbi.nlm.nih.gov/32870154/> – 2020

Sandulovici R, Mircioiu I, Aboul-Enein HY, Manolache M, Mircioiu C, Voicu V, Anuta V. Sources of outlier data in the bioanalytical and clinical part of a piroxicam bioequivalence study. *Int J Clin Pharmacol Ther*. 2020 Nov;58(11):652-663. doi: 10.5414/CP203794. PMID: 32870154. <https://pubmed.ncbi.nlm.nih.gov/32870154/>



● **CONFERENCES AND SEMINARS**

2016 – Novotel Hotel, Bucharest

National Congress of Clinical Research in Romania - First Edition 2016

We were the first initiators of the National Congress of Clinical Research in Romania (CNCCR) developed together with the "Carol Davila" University of medicine and Pharmacy having speakers from international institutions.

<http://www.cnccr.ro>

2017 – Novotel Hotel, Bucharest

National Congress of Clinical Research in Romania - Second Edition 2017

It was the second edition of the National Congress of Clinical Research in Romania (CNCCR) developed together with the "Carol Davila" University of medicine and Pharmacy.

www.cnccr.ro

Dated: 1 sept 2020

Signature: