06 June 2017

Personal Information

Full Name:	Ghazaleh Gouya, MD, Privat Dozent
Country of Residence:	Austria
Current Position:	• Founder/ Owner Gouya-Insights: Consulting in Clinical Development for Life Science Industry • Cardiologist – working in practice in Vienna, Austria
Date of birth	9 August 1971
Nationality	Austria
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Summary

As founder of the Gouya-Insights KG, Ghazaleh Gouya takes leadership in clinical development for biotechnology companies in setting up the clinical development program, seeking scientific advice from competent authorities, creation of clinical operations team and acting as main contact point between sponsor and clinical operation in providing oversight in the conduct of clinical studies and medical data review process, and supporting the finalization of clinical study reports, the publication and application process.

Board certified in Internal Medicine, Cardiology and Clinical Pharmacology, MD, with more than 15 years of clinical research experience. After 6 years of clinical practice in internal medicine and cardiology in UK and Austria Ghazaleh Gouya joined the cardiovascular research team at the Department of Clinical Pharmacology, Medical University Vienna. During her stay at the Medical University Vienna she finalized her training in cardiology focused on heart failure disease management.

During her almost 2 years experience at Quintiles she was involved in leading the Medical Monitoring groups for cardiovascular outcome trials as well as early phase cardiology trials. Ghazaleh has been involved in a number of business development activities where she substantially added to the strategy for the project and protocol development in identifying the best strategy for the right patients at the right site.

While working at the Department of Clinical Pharmacology she gained fundamental clinical research experience (investigator driven and industry sponsored cardiovascular and metabolic studies). She participated in clinical trials as sub- and principal investigator where she was responsible for developing concept, design, protocol, performance, and management strategies for clinical phase I-III trials in cardiovascular and metabolic area. She published more than 30 research papers in peer reviewed journals and 3 book-chapters and actively participated in national and international congresses. In March 2015 she was awarded the title Associate Professor for Internal Medicine from the Medical University Vienna with her habilitation thesis "Efficacy and Effectiveness of Antithrombotic Therapy".

In 2008 she successfully applied together with a large group of representatives of FP7 clinical infrastructures and EFPIA members for a European funded project of education and training in medicines development (www.emtrain.eu). She was scientific head and head of communication of EMTRAIN until 2012.

Formal Educational History

Last Date Attended	Institution Name, Country	Education Level/Degree	Area of Study
04/1997	University of Vienna, Medical Faculty, Austria	MD	Medicine

Licenses and Certifications

- Internal Medicine - Austrian board certified, 2006
- Cardiology - Austrian board certified, 2010
- Clinical Pharmacology - Austrian board certified, 2013

Awards and Honors

- Gerot Prize for special training in heart failure, 2000
- IMI-EU funding for EMTRAIN, 2008
- Associate Professor in Internal Medicine (Thesis "Efficacy and Effectiveness of Antithrombotic Therapy"), March 2015

Relevant Non-Clinical Training

EU-Project:

09/08 – 02/13 - Scientific Head of the Project office of EMTRAIN (European Medicines Training and Research Network, topic 14 of the IMI JU – Innovative medicines initiatives joint undertaken) - Co-lead of communication, information and dissemination (EMTRAIN)

www.emtrain.eu

www.on-course.eu

www.imi-europe.org

Employment History

Date of Employment:	08/1997 - 01/1998
Name of Employer:	Dundee Teaching Hospitals, UK
Job Title:	Junior House Officer
Key Responsibilities:	Medical Care for patients on Urology, Orthopaedic, Burns and Plastic Surgery Departments at. Regular ward rounds, on-call duties.

Date of Employment:	02/1998 - 07/1998
Name of Employer:	St. James's Hospital, Leeds, UK
Job Title:	Junior House Officer

Key Responsibilities:	Medical Care for approx. 120 patients on general medical wards including CCU, general ward rounds, emergency care and emergency on-call duties.
Date of Employment:	09/1998 - 01/2001
Name of Employer:	LKH-Feldkirch, AUT
Job Title:	Resident Internal Medicine
Key Responsibilities:	Medical care and on-call emergency duties for patients on departments of Nephrology, Gastroenterology, CCU, Endocrinology and General Internal Medicine. Heart failure and heart transplant clinic. Sub-investigator in Phase III trials.
Date of Employment:	02/2001 - 06/2001
Name of Employer:	University Innsbruck, Department of Cardiology
Job Title:	Resident Cardiology
Key Responsibilities:	Heart failure and heart transplant clinic (pre- and postheart transplant patient care).
Date of Employment:	07/2001 - 10/2004
Name of Employer:	LKH-Feldkirch, AUT
Job Title:	Resident Internal Medicine
Key Responsibilities:	Medical care and on-call duties for patients in Cardiology and General Internal Medicine (echocardiography, abdominal sonography). Heart failure and heart transplant clinic.
Date of Employment:	03/2005 - 05/2006
Name of Employer:	Medical University Vienna
Job Title:	Resident Internal Medicine
Key Responsibilities:	Cardiovascular Research Associate in Phase I-II trials at the Department of Clinical Pharmacology,clinical rotation to medical intensive care unit
Date of Employment:	06/2006 - 02/2007
Name of Employer:	Medical University Vienna, Department of Clinical Pharmacology
Job Title:	Consultant for Internal Medicine
Key Responsibilities:	Research associate performing investigator driven and sponsored Phase I-II trials.
Date of Employment:	03/2007 - 11/2009
Name of Employer:	Medical University Vienna, Department of Cardiology
Job Title:	Resident Cardiology
Key Responsibilities:	Cardiac intensive care unit, heart failure clinic, echocardiography

Date of Employment:	12/2009 - 06/2010
Name of Employer:	KA-Rudolfstiftung Vienna, Department of Cardiology
Job Title:	Resident Cardiology
Key Responsibilities:	Coronary angiography, echocardiography, cardiac ward rounds

Date of Employment:	11/2010 - 02/2011
Name of Employer:	Medical University Vienna, Heart Transplant Unit
Job Title:	Consultant Cardiologist
Key Responsibilities:	post-heart transplant patient care

Date of Employment:	07/2010 - 10/2013
Name of Employer:	Medical University Vienna, Department of Clinical Pharmacology
Job Title:	Resident Clinical Pharmacology
Key Responsibilities:	Design, protocol development, performance of cardiovascular and metabolic investigator driven and sponsored clinical trials. First in human clinical trials, pharmacodynamic models for coagulation and endothelial function.

Date of Employment:	11/2013 - 10/2014
Name of Employer:	Medical University Vienna
Job Title:	Consultant Cardiologist and Clinical Pharmacologist
Key Responsibilities:	Deputy head of section cardiovascular research, principal investigator in academic and sponsored phase I-III trials for concept, design, planning, performing and analysis of clinical trials. Lecturer in Cardiology and Clinical Pharmacology. Representative of the assistant staff, coordinator of the journal club.

Date of Employment:	11/2014 – 08/2016
Job Title:	Associate Medical Director
Business Title:	Cardiovascular and Metabolic Diseases
Key Responsibilities:	Medical advisor and scientific consultant for cardiovascular and metabolic clinical trials: • Provide medical, clinical and scientific advisory expertise in cardiovascular projects • Ensure project medical oversight, including support of Project Managers, Clinical Trial Leaders, and CRAs, guidance to investigative sites on trial related medical issues, and resolution of key clinical issues • Provide internal and external therapeutic related educational services in support of all branches of Quintiles business • Provide medical consultancy for the design, preparation or review of protocol, investigator brochure, clinical expert reports and documents submitted to the regulatory authorities

Clinical Development Leadership Gouya Insights

- Since 8/2016 Therapeutic Indication: gynecological Infections

Drug Class: Antifungal medication

Geographic Region: Austria

Role: Clinical Development Lead

Key Responsibilities: Creation of the clinical development program, seeking scientific advice from competent authorities, creation of clinical operations team and acting as main contact point between sponsor and clinical operation in providing oversight in the conduct of clinical studies and medical data review process, and supporting the finalization of clinical study reports, the publication and application process

- Since 11/2016 Therapeutic Indication: Slow healing foot ulcers

Drug Class: Biological wound dressing

Geographic Region: Austria/ middle Europe

Role: Clinical Development Lead

Key Responsibilities: Creation of the clinical development program, seeking scientific advice from competent authorities, creation of clinical operations team and acting as main contact point between sponsor and clinical operation.

- 12/2016 – 05/2017 Therapeutic Indication: Endstage Renal Failure

Drug Class: patent-protected solution for peritoneal dialysis

Geographic Region: Austria

Role: Medical Data Review

Key responsibilities: Medical data review plan, medical data review of data listings, providing data query listings, confirmation of query resolution, participation in data monitoring board.

- Since 02/ 2017 Therapeutic Indication: fat graft

Drug Class: biological

Geographic Region: Austria

Role: medical Writing (protocol, informed consent form (ICF))

Key responsibilities: Literature search, developing final protocol and ICF for submission

Clinical Trial Experience

Study Phase:	Phase 2
Indication:	Acute coronary syndrome
Drug Class:	Lipid lowering medication
Geographic Region:	Europe/Middle East/Africa (EMEA) and North America
# of Sites:	110
# of Patients:	1200
Role:	Global Medical Advisor

Key Responsibilities:	Lead of the Medical services, protocol development, investigator and team training, medical monitoring, data review, pharmacovigilance

Study Phase:	Phase 3
Indication:	Primary and secondary prevention in patients at high risk for cardiovascular events
Drug Class:	Lipid lowering medication
Geographic Region:	Global
# of Sites:	210
# of Patients:	13000
Role:	Global Medical Advisor
Key Responsibilities:	Lead of the Medical services, protocol development, investgator and team training, medical monitoring, data review, recruitment and IP retention strategy,

Study Phase:	Phase 2
Indication:	Complex cardiac surgery
Drug Class:	Immunmodulation
Geographic Region:	Europe/Middle East/Africa (EMEA) - Germany only
# of Sites:	10
# of Patients:	100
Role:	Medical Advisor
Key Responsibilities:	Lead of the Medical services, protocol development, investigator and team training, medical monitoring, data review, pharmacovigilance

Study Phase:	Phase 3
Indication:	Pediatric Hypertension
Drug Class:	RAAS inhibitor
Geographic Region:	Europe/Middle East/Africa (EMEA) and South Africa
# of Sites:	60
# of Patients:	270
Role:	Medical Advisor
Key Responsibilities:	Lead of the Medical services, protocol development, investigator and team training, medical monitoring, data review, pharmacovigilance

Study Phase:	Phase 2
Indication:	Pediatric venous thromboembolism
Drug Class:	Novel oral anticoagulant

Geographic Region:	Global
# of Sites:	45
# of Patients:	270
Role:	Global Medical Advisor
Key Responsibilities:	Lead of the Medical services, protocol development, investigator and team training, medical monitoring, data review, pharmacovigilance

Study Phase:	Phase 3
Indication:	Heart Failure
Drug Class:	Diuretic and glucose lowering
Geographic Region:	global
# of Sites:	110
# of Patients:	8000
Role:	Global Medical Advisor
Key Responsibilities:	Lead of the Medical services, protocol development, investigator and team training, site ID

Study Phase:	Phase 2
Indication:	Acute coronary syndome
Drug Class:	Lipid lowering medication
Geographic Region:	Europe/Middle East/Africa (EMEA) and North America
# of Sites:	15
# of Patients:	80
Role:	Global Medical Advisor
Key Responsibilities:	Lead of the Medical services, protocol development, investigator and team training, medical monitoring, data review, pharmacovigilance

Study Phase:	Phase 2
Indication:	Diabetes Mellitus
Drug Class:	Diabetic Medications
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Small
# of Patients:	Small
Role:	Medical Advisor

Key Responsibilities:	Academic research organization: Conduction of clinical trials (Phase I-IV) as subinvestigator including patient/subject recruitment, conduction of study related tests.
Study Phase:	Phase 1
Indication:	Atrial Fibrillation
Drug Class:	Other
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Small
# of Patients:	Small
Role:	Medical Advisor
Key Responsibilities:	Sub-investigator involved in protocol development, submission to the ethics committee and official bodies, patient/subject recruitment, conduction of study related tests, data analysis, data interpretation and publication.
Study Phase:	Phase 3
Indication:	Atrial Fibrillation
Drug Class:	Other
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Small
# of Patients:	Small
Role:	Medical Advisor
Key Responsibilities:	Academic research organization: As sub-investigator involved in protocol development, submission to the ethics committee and official bodies, patient/subject recruitment, conduction of study related tests, data analysis, data interpretation and publication.
Study Phase:	Phase 2
Indication:	Hypertensive disorder
Drug Class:	Drug / Device Combination Products
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Small
# of Patients:	Small
Role:	Medical Advisor
Key Responsibilities:	Academic research organization: Co-Investigator for clinical trial in device therapy for hypertension involved in patient/subject recruitment, conduction of study related tests, training of staff.

Study Phase:	Phase 1
Indication:	Influenza A (H1N1)
Drug Class:	Vaccines - Antiviral
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Medium
# of Patients:	Medium
Role:	Medical Advisor
Key Responsibilities:	Academic research organization: Sub-investigator involved in patient/subject recruitment, conduction of study related tests.

Study Phase:	Phase 1
Indication:	Bacterial Infectious Disease
Drug Class:	Anti-inflammatory Drugs
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Small
# of Patients:	Small
Role:	Medical Advisor
Key Responsibilities:	Academic research organization: as principal including protocol development, submission to the ethics committee and official bodies, patient/subject recruitment, conduction of study related tests, data analysis, data interpretation and publication.

Study Phase:	Phase 1
Indication:	Heart Failure
Drug Class:	Antihypertensive
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Small
# of Patients:	Small
Role:	Medical Advisor
Key Responsibilities:	Academic research organization: Sub-investigator involved in protocol development, submission to the ethics committee and official bodies, patient/subject recruitment, conduction of study related tests, data analysis, data interpretation and publication.

Study Phase:	Phase 2
Indication:	Diabetic Peripheral Neuropathy

Drug Class:	Analgesics / Narcotics
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Medium
# of Patients:	Medium
Role:	Medical Advisor
Key Responsibilities:	Academic research organization: Conduction of clinical trials (Phase I, II, III and IV), academic and industry sponsored as principal and sub-investigator including protocol development, submission to the ethics committee and official bodies, patient/subject recruitment, conduction of study related tests, data analysis, data interpretation and publication.

Study Phase:	Phase 1
Indication:	Bacterial Infectious Disease
Drug Class:	Anti-inflammatory Drugs
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Small
# of Patients:	Small
Role:	Medical Advisor
Key Responsibilities:	Academic research organization: Sub-investigator involved in protocol development, submission to the ethics committee and official bodies, patient/subject recruitment, conduction of study related tests, data analysis, data interpretation and publication.

Study Phase:	Phase 2
Indication:	Lipid Metabolism Disorders
Drug Class:	Other
Geographic Region:	Europe/Middle East/Africa (EMEA)
# of Sites:	Small
# of Patients:	Small
Role:	Medical Advisor
Key Responsibilities:	Academic research organization: Conduction of clinical trials (Phase I, II, III and IV), academic and industry sponsored as principal and sub-investigator including protocol development, submission to the ethics committee and official bodies, patient/subject recruitment, conduction of study related tests, data analysis, data interpretation and publication.

Therapeutic Experience

Therapeutic Area:	Cardiovascular

Years Experience:	15.5
Indication:	Heart Disease
Years Experience:	15.5
Describe Experience:	Medical care for cardiac in- and outpatients in various hospitals; cardiovascular research in platelet function and antiplatelet therapy

Therapeutic Area:	Cardiovascular
Years Experience:	15.5
Indication:	Heart Failure
Years Experience:	15.5
Describe Experience:	Clinical: Heart failure disease management for in- and outpatients. Intensive care hemodynamic management, device therapy, echocardiography. Pre- and post-heart transplant Management. Research: Biomarkers, nutrition and epidemiology

Therapeutic Area:	Cardiovascular
Years Experience:	15.5
Indication:	Hyperlipidemia
Years Experience:	10
Describe Experience:	Primary prevention and secondary prevention lipid management of in- and outpatients.

Language(s)

Language	Speaking	Reading	Writing
English	Fluent	Fluent	Fluent
German	Fluent	Fluent	Fluent
French	Basic	Basic	Basic
Italian	Basic	Basic	Basic
Persian	Business Level	Basic	Basic

Publications

- Mesgarpour B, Gouya G, Herkner H, Reichardt B, Wolzt M. A population-based analysis of the risk of drug interaction between clarithromycin and statins for hospitalisation or death. Lipids Health Dis. 2015 Oct 24;14:131.
- Wolzt M, Gouya G, Sator M, Hemetsberger T, Irps C, Rettenbacher M, Vcelar B. Comparison of pharmacokinetic and safety profiles between Bemfola(®) and Gonal-f (®) after subcutaneous application. Eur J Drug Metab Pharmacokinet. 2015 Jan 30.
- Told R, Schmidl D, Palkovits S, Boltz A, Gouya G, Wolzt M, Witkowska KJ, Popa-Cherecheanu A, Werkmeister RM, Garhöfer G, Schmetterer L. Antioxidative capacity of a dietary supplement on retinal hemodynamic function in a human lipopolysaccharide (LPS) model. Invest Ophthalmol Vis Sci. 2014 Dec 18;56(1):403-11.
- Storka A, Vcelar B, Klickovic U, Gouya G, Weisshaar S, Aschauer S, Bolger G, Helson L, Wolzt M. Safety, tolerability and pharmacokinetics of liposomal curcumin in healthy humans. Int J Clin Pharmacol Ther. 2015 Jan;53(1):54-65.
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- Aschauer S, Gouya G, Klickovic U, Storka A, Weisshaar S, Vollbracht C, Krick B, Weiss G, Wolzt M. Effect of systemic high dose vitamin C therapy on forearm blood flow reactivity during endotoxemia in healthy human subjects. Vascul Pharmacol. 2014 Apr;61(1):25-9.
- Gouya G, Arrich J, Wolzt M, Huber K, Verheugt FWA, Gurbel PA, Pirker-Kees A., Siller-Matula J. Antiplatelet treatment for prevention of cerebrovascular events in patients with vascular diseases: a systematic review and meta-analysis. Stroke. 2014 Feb;45(2):492-503.
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- Storka A, Vcelar B, Klickovic U, Gouya G, Weisshaar S, Aschauer S, Helson L, Wolzt M. Effect of liposomal curcumin on red blood cells in vitro. Anticancer Res. 2013 Sep;33(9):3629-34.
- Wolzt M, Gouya G, Kapiotis S, Becka M, Mueck W, Kubitza D. Open-label, randomized study of the effect of rivaroxaban with or without acetylsalicylic acid on thrombus formation in a perfusion chamber. Thromb Res. 2013 Aug;132(2):240-7.
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IDMS-traceable creatinine based MDRD as well as Mayo Clinic quadratic equation estimates. Clin Chim Acta. 2007 Mar;378(1-2):71-7.

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- Gouya G, Hülsmann M. Die kardiale Kachexie. Eine Folge der chronischen Herzinsuffizienz. Wiener Klinisches Magazin. Volume 12, Number 3 / Juni 2009.
- Gouya G, Hartmann G, Faè P, Tauber M, Holzmüller H, Benzer W, Lang A, Schuster A, Drexel H, Offner FA. A case of fulminant post-transplant lymphoproliferative disorder and septicemia. Clin Transplant. 2006 Mar-Apr;20(2):261-4.
- **Book-chapters**:
- Gouya G, Wolzt M: Cardiovascular disease and ocular manifestations. In: Schmetterer L (ed), Ocular Blood Flow. Springer, Berlin 2012.
- Gouya G. Current Topics in Clinical Pharmacology (Müller M. et al); Special situations, market fragmentation 2: sex – differences; Example: CHD. Springer Verlag 2010-revised 2016

- Gouya G, Wolzt M: Rationelle Abklärung des Hypertonikers und Risikostratifizierung. In: Auer J (ed), Hypertoniebehandlung in der Praxis. UNI-MED Verlag AG, ISBN 978-3-8374-1081-5, 2008.