

Firas M. Younis

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Synopsis:

- **Professional Skills:** Nearly 20 years of academic and industrial experience in research and development, the last of which, is my current position **as DMPK project lead at Teva Pharmaceutical**. Coordinating planning and managing nonclinical IND enabling PK studies. Coordinating multiple activities and working with different functional groups while maintaining vigilance on timelines without compromising study integrity; sample bioanalysis, PK data analysis, NCA, *PK/PD*, BA and BE. Support of clinical phase study design, and dose selection/escalation. **Preparing regulatory documents for submission IND, IB and NDA**. Good presentation skills with to the point presentation preparation. During my PhD studies, I have worked with KOL in the field of diabetes and hypertension, as my doctorate thesis was in the treatment of *Diabetes and Hypertension*. Throughout my career I have worked in research and development for several other diseases including *MS, PD, antipsychotics and pain*.
 - **Academic Skills:** Teaching skill included practicing as teacher assistant for couple of courses during my Graduate Studies. I have participated in many review sessions for different academic journals, and I have attended several international conferences, research presentation. I have taught and directed high school student to write scientific seminar.
 - **Managerial Skills:** ability to plan, lead, and guide outsourced CROs and scientists into effective study performance meeting project interests and needs, through effective communications, and sound scientific conveyed reasoning. Effective communication skills with ability to multitask and communicate with many stakeholders. Managing several projects as well as, 3-5 people at industrial settings, with great attention to professional details of the projects finance, fund allocation, timelines and data integrity. Currently in the process of obtaining a "**Project Manager Professional (PMP)-certificate**" and already have a **GCP** certificate.
 - **Social:** Ambitious, Self-driven, Fast learner, Motivated and Sociable. Interested in a position involving managerial and scientific leadership expertise.
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Work Experience:

01/06/2021-Present

Business and Research Development Manager
Pharma-logica, Ltd

Heading the department of R&D department, seeking client with potential developing projects in the field of pharmaceutical development. Provide a professional, tailored study design to meet project objectives and achieve the project's goals based on scientific merits, performance feasibility while targeting precise and deliverable end points. Deliver scientific professional consultation, designing and selection of suitable experimental model, and orchestrating comprehensive study protocol meeting study objectives. Professional role include offering proficiency in pharmaceutical development and regulatory requirements needed to bring products from the bench to clinical development.

1/11/2015-03/2021:

Manager, DMPK Project Lead

R&D drug development

Teva Pharmaceutical, Abic Natanya, Israel

As DMPK nonclinical Lead at Teva pharmaceutical I managed 3 projects extended over different product development phases, including: Managing all preclinical DMPK/ADME activities of the project during development, starting from proof of concept, conducting and planning none-GLP and GLP IND-enabling PK studies at different CROs all over the world. Working closely with different functional groups including nonclinical safety, pharmacology and bioanalytics to ensure providing results within timelines while avoiding falling on project critical path. Worked with clinical pharmacology team, providing essential support for first in human studies/clinical phase 1; clinical dose selection based on preclinical obtained data, PK NCA analysis of clinical data and support decision making on dose escalation. Support advanced clinical phases 3 on PK sample transfers from clinical sites, samples bioanalysis, and data transfer.

Nonclinical ADME regulatory documents writing and preparation; IND, IB, DSUR, and NDA. Preparation of briefing book (BB) for type B/C guidance meetings with FDA, mitigating with FDA, and participating in a type C meeting with the agency.

04/2013-1/11/2015:

Project Leader

Tel-Aviv University, Ramat Aviv, Tel-Aviv, Israel

Project: Preventive Effect of Empagliflozin on the development of Diabetes and **Cardiovascular** pathologies in CRDH rats.

- Preparation of scientific study proposal, financial estimate and study time for **Boehringer Ingelhiem Pharmaceuticals** .
- Meeting with BI leading scientist; Finalizing study protocol and financial coverage
- Supervising two PhDs individuals working on the project; ensuring timely experimental performance, quality of data collected, and providing technical support, while maintaining vigilance of the study deadlines.
- Preparing midterm scientific reports along with statements of progress to counterpart scientist at BI.

02/2012-05/2013:

Pre-Clinical Study Director

PharmaseedLtd, Ness-Ziona, Israel

- Director of multi-disciplined pre-clinical studies/projects at the pharmacological levels in various diseases including **Parkinson Disease**, **Multiple Sclerosis**, **Diabetes**, PK/PD, as well as, investigating pleiotropic effects of stem cells and other products on different animals models in **GLP** settings.
- Directing a study involving combining intranasal delivery technology for Parkinson Disease in animals
- Responsibilities including:
 - Study design/planning, protocol writing, financial allocation

- o Establishing scientific consortium per project, presenting the projects' scientific essence, milestones, while coordinating interdepartmental resources, as well as outsourcing providers and services.
- o **Managing 3-6 technicians**, supervising technicians and scientist to perform studies ensuring project progress is done coherently and consistent with guidelines and protocol. Coordinating documentation of data analysis, while providing technical advices, support and problem solving.

04/2006-10/2006:

Project Coordinator
At Tel Aviv University and Bioline Pharmaceuticals

- Project:** Effect of Allicin derivative given orally on metabolic syndrome features in CRDH animals
- Coordinated a joint project between Bioline Pharmaceuticals and the laboratory of Professor Rosenthal at Tel-Aviv University
 - Managing project scope, deliverables and the time lines, with emphasis on the scientific rationales supporting study performance.

11/2004-09/2005:

Research Scientist
Tel Aviv University, Ramat Aviv, Tel-Aviv, Israel

- Working with unique animal model expressing both hypertension and type II diabetes to elucidate pharmacological approaches using antihypertensive and anti-hyperglycemic treatments.

10/2003-10/2004:

Research Scientist/PhD Study
Tel Aviv University, Ramat Aviv, Tel-Aviv, Israel
Mintor: Professor Amos Korczyn

- Dissertation: A possible autonomic system regulatory pathway of the immune response to induced EAE in mice, through nicotinic $\alpha 7$ acetylcholine receptor.
- Developed EAE model in nicotinic **$\alpha 7$ AchR knock-out** animals
- Use of pharmacological interventions including immunosuppressant treatments and follow through for validation of outcome.

Work was terminated due to financial constrains.

02/2000-08/2003:

Research Scientist
D-Pharm Ltd; Kiryat Weizmann, Rehovot, Israel

Responsible for model development and for pharmacological (PD/PK) assessment of newly synthesized compounds at D-Pharm, managing several studies and supervising the work of technicians:

Skills:

- Developed pain models and neuropathic nerve models, Anxiety and Depression Model in Gerbils, an autoimmune disease model in mice and rats; Encephalomyelitis Autoimmune Disease (EAE), BBB penetration of lipid derivatives into the brain.

- *PK/PD PROFILING OF DRUGS (ADME)*

Academic Teaching experience:

Teacher assistant:

2007-2009; Tel Aviv University;; General Physiology course for sophomore medical students, including laboratory guidance and monitoring.

2007-2008: Teacher assistant: Tel Aviv University, , Principles of Pharmacology; including introduction and problem solving.

Research Assistant:

1997-1998: Hebrew University of Jerusalem: Principles of the Neurodegenerative Disease; 1998,

Other work experience

Medical Laboratories at different Hospitals and health providing centers; including: the American medical Laboratory in Hertzylia, AMC in Rishon Letzion, and the Megav Ledach in Jerusalem

Recent Job:

01/2012-Present:

Helil Yaffe Medical Center

Hadera, Israel

- Clinical Biochemistry
- Hematology
- Blood typing
- Bacteriology

Additional Professional Activities:

- I was part of a collaborate study with the laboratory of Professor David Merilman, the Weizmann Institute of Science, on a pilot study examining the efficacy of a novel compound with an allicin (garlic) derivative on hypertension and hyperglycemia
- *Younis, et al.J Clin Hypertens* 2010 June;12(6):451-5.
- Served as an advisor for ***Insight Biopharmaceuticals, Ltd***; designing an experimental setting and performance of EAE model in mice using extracted mice spinal cord homogenate, (2009).
- Coordinated the pharmacological aspect of a collaborate project between ***Eli & Lilly*** in Indianapolis and ***D-phram*** involving improved BBB penetration of anxiety and depression drugs coupled with lipid derivatives. Served as a delegate scientist to Eli & Lilly in Indianapolis for experimental and data synchronization/comparison. (2002)
- Attended courses in a pharmacokinetics at the Hebrew University School of Pharmacy. **Course Title:** Pharmacokinetics and Pharmacodynamics. (2001)
- Certified to work with Radioactive materials; Attended a teaching course of GLP for handling Radioactive materials at ***Nahal Sorek-Yavni***; (2000)
- Participated in a collaborate study and research with a team led by Dr. Philip Stahel, (Divisions of Trauma Surgery and Research, Department of Surgery, University Hospital, Zurich, Switzerland), in the field of Head Trauma and the Secondary Damage (1998/9).

- Holder of a permanent certification from the Ministry of Health to work in clinical laboratories; "Status Recognition-Hakart Maamad"- since 1997.

Education:

2005-2010: **PhD in Pharmacology and Physiology**

Tel-Aviv University, Ramat Aviv -Israel

Advisors: Professor Talma Rosenthal and Professor Yoram Oron, Department of Physiology and Pharmacology, Sackler School of Medicine.

Dissertation Title: Killing Two Birds in One Stone; Telmisartan, an ARB and a Partial PPAR γ Agonists, Ameliorates Hyperglycemia via Modification of Metabolic Pathways at Tissue levels.

Published several articles as first author in the field of my dissertation.

1996-1998: **Masters of Science- in Basic Medical Sciences/Pharmacology; M.Sc.**

The Hebrew University, Jerusalem- Israel

Advisor: Professor Ester Shohami

Thesis Title: Acute Toxicity of TNF α after Closed Head Injury; Novel Treatment.

1992-1995: **Bachelor Degree of Science in Biochemistry; B.Sc.**

Washington State University, Pullman WA, U.S.A.

1990-1991: **Associate Degree in Liberal Arts; AA Degree**

Northern Marianas Collage of Saipan, Saipan (Common Wealth of the Northern Marianas Islands); U.S.A

Awards and Honors:

2006-2009: **The Institute of Higher Learning of Israel:**

Three years awarded scholarship for excellent students (granted for Arabs and other Minorities)

2006: **Yarid Hamahkar**, Tel-Aviv University

Awarded certificate honor for best presented poster

2009-2010: **Vatat Scholarship**, Tel-Aviv University

Awarded based on the merit of achievements and dissertation progress

2010: **Dean of School of Medicine**, Tel-Aviv University

Scholarship of the Dean

PUBLICATIONS:

Patent Publications:

1. Inventor in an International Patent Publication No. WO03/000173, published on January, 2003. Title: Use of Branched Chain Fatty Acid and Derivatives Thereof for the Treatment of Pain.
2. Inventor in a U.S. Patent No. 6,518,311 grant date: 11th of February, 2003. Title: Use of Branched Chain Fatty Acid and Derivatives Thereof for the Treatment of Pain.

Journal Articles:

1. Victoria Trembovler, Elie Beit-Yannai, **Firas Younis**, Ruth Gallily, Michal Horowitz, Esther Shohami. Antioxidants Attenuate Acute Toxicity of Tumor Necrosis Factor- α Induced by Brain Injury in Rat. *Journal of Interferon and Cytokines Research*, **1999**, 19:791-795.
2. Philip F Stahel, Esther Shohami, **Firas M Younis**, Karin Kariya, Viviane I Otto, Philipp M Lenzlinger, Maurice B Grosjean, Hans-Pietro Eugster, Otmar Trentz, Thomas Kossmann and Maria C Morganti-Kossmann. Experimental Closed Head Injury: Analysis of Neurological Outcome, Blood-brain Barrier Dysfunction, Intracranial Neutrophil Infiltration, and Neuronal Cell Death in Mice Deficient in Genes for Pro-Inflammatory Cytokines. *Journal of Cerebral Blood Flow Metab.* **2000** Feb; 20(2):369-80.
3. E. Dvir, J. E. Friedman, J. Y. Lee, J. Y. Koh, **F. Younis**, S. Raz, I. Shapiro, A. Hoffman, A. Dahan, G. Rosenberg, I. Angel, A. Kozak, and R. Duvdevan. A Novel Phospholipid Derivative of Indomethacin, DP-155 [Mixture of 1-Steroyl and 1-Palmitoyl-2-{6-[1-(p-chlorobenzoyl)-5-methoxy-2-methyl-3-indolylacetamido]hexanoyl}-sn-glycero-3-phosphatidyl Choline], Shows Superior Safety and Similar Efficacy in Reducing Brain Amyloid β in an Alzheimer's Disease Model. *JPET* 318:1248-1256, **2006**.
4. **Younis F**, Kariv N, Nachman R, Zangen S, Rosenthal T. Telmisartan in the treatment of Cohen-Rosenthal Diabetic Hypertensive rats: the benefit of PPAR γ agonism. *Clin Exp Hypertens.* **2007** Aug; 29(6):419-26.
5. **Firas M. Younis**; Naftali Stern; Rona Limor; Yoram Oron; Sarah Zangen; Talma Rosenthal. Telmisartan Ameliorates Hyperglycemia and Metabolic Profile in non-obese Cohen Rosenthal Diabetic Hypertensive Rats, Via PPAR γ Activation. *Metabolism.* **2010** Aug;59(8):1200-9.
6. **Firas Younis**; David Mirelman; Aharon Rabinkov; Talma Rosenthal. S-Allyl-mercapto-captopril, A Novel Compound, in the Treatment of the Cohen-Rosenthal Diabetic Hypertension Rats" *J Clin Hypertens* **2010** June; 12(6):451-5.
7. Talma Rosenthal, **Firas Younis**, Ariela Alter. Combating combination of hypertension and diabetes in different rat models. *Pharmaceuticals* **2010**, 3(4), 916-939.
8. **Younis F**, Oron Y, Limor R, Stern N, Rosenthal T. Prophylactic treatment with Telmisartan induces tissue-specific gene modulation favoring normal glucose homeostasis in Cohen-Rosenthal diabetic hypertensive rats. *Metabolism* **2011** Aug 4.
9. **Firas M. Younis**, Tamar Blumenthal-Katzir, Kenneth Hollander, Nikolaos Grigoriadis, Olga Touloumi, Roza Lagoudakic, Talma Rosenthal. Telmisartan-mediated metabolic profile conferred brain protection in diabetic hypertensive rats as evidenced by magnetic resonance imaging, behavioral studies and histology *European Journal of Pharmacology*, Volume 789, 15 October **2016**, Pages 88-97.

10. **Firas Younis**, Jonathan Leor, Zaid Abbassi, Natalie Landa, Lea Rath, Kenneth Hollander, Nili Naftali-Shani, Talma Rosenthal. Beneficial Effect of the SGLT2 Inhibitor Empagliflozin on Glucose Homeostasis and Cardiovascular Parameters in the Cohen Rosenthal Diabetic Hypertensive (CRDH) Rat. *J Cardiovasc Pharmacol Ther*, 2018 Jul; 23(4):358-371.

Published abstracts/Poster Presentation:

1. R. Duvdevani; E. Dvir; **F.M. Younis**; S.S. Russo; S. Raz; L. Bello; M. Polyak; I. Shapiro; V. Ioffee; K. Ulanenko; O. Strikovskiy; O. Karpov; A. Kozak; I Angel (2003). DP-155- A Phospholipid Derivative of Indomethacin, Exhibits an Improved Therapeutic Index. 33rd Annual Meeting of the Society for Neuroscience, November 2003, New Orleans, LA.
2. **F.M. Younis**, N. Kariv, T. Rosenthal. Dual Effect of Chronic Treatment with Telmisartan on hypertension and Hyperglycemia in Cohen Rosenthal Diabetic Hypertensive Rats, Cohen Diabetic Rats and SHR. *Journal of Hypertension*, 2006, Vol 24 (Suppl 4); S387
3. **F. Younis**, T. Blumenfeld-Katzir, T. Rosenthal, Y. Asaf. Telmisartan Bestowed Brain Protection in Cohen-Rosenthal Diabetic Hypertensive (CRDH) rats as Revealed by Magnetic Resonance Imaging. *Journal of Hypertension* 2008, Vol. 26 (suppl. 1); S280.
4. **Firas Younis**, Yoram Oron, Naftali Stern, rona Limor, Talma Rosenthal. Effects of Telmisartan and Valsartan Treatment on Hypertensive-Hyperglycemic Rats; A Possible PPAR γ Additive Effect. *The Journal of Clinical Hypertension*, Supp. A Vol. II NO 4 April 2009, A119.
5. **F. Younis**, D. Merilman, T. Rosenthal. S-Allyl-Mercapto-Captopril in the Treatment of the Cohen-Rosenthal Diabetic Hypertensive Rats. *Journal of Hypertension* 2009, Vol 27 (suppl 4), S136.
6. **Firas Younis**, Zaid` Abassi, Kenneth Hollander, Eric Mayoux, Natalie Landa-Rouben Talma Rosenthal. Glomerular Protective Effect of and Pancreatic Preservation Induced by Preventive Treatment with Empagliflozn in Cohen Rosenthal Diabetic Hypertensive Rats. ISE/ESH meeting Athenes, 2014.
7. **Firas Younis**, Kenneth Hollander, Eric Mayoux, Natalie Landa-Rouben, Yoni Lior, Rachel Nachman, Talma Rosenthal. Effect of Prophylactic Treatment with Empagliflozin on Cardiac Function and Diabetes in CRDH Rats. ADA 74th Meeting, San Francisco, 2014.
8. **Firas Younis**, Zaid Abassi, Eric Mayoux, Kenneth Hollander, Lea Rath-Wolfson, Talma Rosenthal.. Empagliflozin, a Selective SGLT2 Inhibitor, Ameliorated Hyperglycemia and Insulin Resistance, while Preserving the Integrity of Pancreas and Kidney in CRDH rats. EADS meeting in Vienna, 2014.

Computer Skills:

- Microsoft Office (word, excel, PowerPoint)
- knowledge of a professional softwares; SPSS, GraphPad prism, and PK softwares: PK sim and phoenix WinNonlin

Languages:

- Proficient English (reading, writing, speaking)
- Proficient Hebrew (reading, writing, speaking)
- Proficient Arabic (reading, writing, speaking)