CURRICULUM VITAE

PERSONAL INFORMATION

Full name: Maurizio Sessa Date of birth: 04/02/1990

Nationality: Italian

Spoken languages: Italian (mother tongue), English (fluent), Danish (intermediate)

• EDUCATION

2021 Universitetspædagogikum

Department of Drug Design and Pharmacology, University of Copenhagen, Copenhagen,

Denmark

2017 PhD in Translational Medicine

Department of Translational Medicine, University of Campania "L. Vanvitelli", Napoli,

Italy.

PhD supervisors: Prof. Francesco Rossi and Prof. Christian Torp-Pedersen

2017 Certified program in Regulatory Affairs

Department of Economy and Health, Donau Universität Krems, Krems, Austria

2014 Master in Pharmacy

Department of Translational Medicine, Second University of Naples, Napoli, Italy

• RESEARCH METRICS

Scopus Author ID: https://www.scopus.com/authid/detail.uri?authorId=56355170100

ORCID: https://orcid.org/0000-0003-0874-744;

H-index: 18 (Scopus) Citations: 915 (Scopus)

Published articles in peer-reviewed journals with impact factor: 79

First authorships: 23 Last authorships: 15

• GROUP LEADERSHIP

Since 2020, I am leading a new research group (Drug Safety Group) at the Department of Drug Design and Pharmacology, University of Copenhagen. Currently (latest update: Tuesday, 13 June 2023), the group is composed of 1 postdoctoral researchers, 3 PhD Students, 1 Erasmus+ Trainee, and 5 master's students. I have received formal training in the leadership of a research group with the course entitled "Leading Research" sponsored by the Department of Drug Design and Pharmacology at the University of Copenhagen.

• CURRENT POSITION

2019 - Tenure Track Assistant Professor of Pharmacovigilance and Pharmacoepidemiology

ongoing Department of Drug Design and Pharmacology, University of Copenhagen, Copenhagen,

Denmark

• PREVIOUS POSITIONS

2018 – 2019 Postdoctoral researcher in Pharmacovigilance and Pharmacoepidemiology

Department of Drug Design and Pharmacology, University of Copenhagen, Copenhagen,

Denmark

2017 - 2018 Postdoctoral researcher in Pharmacovigilance and Pharmacoepidemiology

Department of Translational Medicine, University of Campania "L. Vanvitelli", Napoli,

Italy

SUPERVISION OF GRADUATE STUDENTS AND POSTDOCTORAL FELLOWS

2018 – 2022 Number of postdoctoral researchers: 3

Number of PhD students: 3 Master's Students: 20 Role: Main Supervisor.

Where: Department of Drug Design and Pharmacology, University of Copenhagen,

Denmark.

• TEACHING ACTIVITIES

In the period 2018-2022, I have been course coordinator and lecturer for courses at all educational levels, from bachelor to PhD at the University of Copenhagen, Atrium, University of Sorbonne, and Karolinska Institutet. Courses taught include:

- 1) Fundamentals of register-based pharmacoepidemiology: evidence synthesis, data sources, and study design (PhD course course coordinator).
- 2) Pharmacovigilance and Pharmacoepidemiology (Elective course course coordinator).
- 3) Register-based research in Pharmacoepidemiology (Elective course course coordinator).
- 4) Design and analysis of experiments (Elective course lecturer).
- 5) Methods and Procedures in Clinical Drug Development (Elective course lecturer).
- 6) Regulatory aspects of Pharmacovigilance (Elective course lecturer).
- 7) Tools in signal detection (Elective course lecturer).
- 8) AI and Big Data in Drug Safety (Elective course course coordinator).
- 9) Fundamentals of drug utilization research using real-world data (PhD course course coordinator).
- 10) Fundamentals of Pharmacoepidemiology using multi-country data sources (PhD course course coordinator).

• ORGANISATION OF SCIENTIFIC MEETINGS

2023	Organizing committee - International Society for Pharmacoepidemiology Mid-year meeting
	2023 - Reykjavik, Iceland
2022	Organizing committee - International Society for Pharmacoepidemiology Mid-year meeting
	2022 - Reykjavik, Iceland
2021	DRA Symposium on Data science tools in pharmaceutical research with emphasis on
	machine learning (ML) and artificial intelligence (AI) - Copenhagen, Denmark
2021	Chairman of the sessions "Rise of the machines: Big data analytics and machine learning in
	pharmacoepidemiology" and "Metabolic Syndromes and Pharmacoepidemiology" -
	International Society for Pharmacoepidemiology Mid-year meeting 2021
2019 - 2022	Chair of the organizing committee – Yearly seminar of the Metabolism and Inflammation
	Research Cluster (MIRC) Symposium - Copenhagen, Denmark

• INSTITUTIONAL RESPONSIBILITIES

External Institutional responsibilities:

Role: Opponent PhD Thesis; Thesis: pharmacoepidemiological studies iof rheumatoid arthritis – Methodological Considerations and Applications. Place: Karolinska Institutet

Institutional responsibilities at the University of Copenhagen:

2020-	Role: Representative of the Pharmaceutical Data Science Committee; Activities: planning
ongoing	pharmaceutical data science courses at the Faculty of Health and Medical Sciences.
2020-	Role: Chair of the Young Pharma Forum; Activities: support career development of young
ongoing	researcher at the Faculty of Health and Medical Sciences.
2019-	Role: Core member of the Metabolism and Inflammation and Personalized medicine
ongoing	Research Clusters, Activities: promote the development of research pipeline in personalized
	medicine, metabolism, and inflammation using real-world data.

REVIEWING ACTIVITIES

2022	Review Board member for grants sent the ZonMw 'Open Competition Call 11', a grant round intended for curiosity-driven scientific research within the field of Rational
	Pharmacotherapy - Dutch Research Council.
2017-	Review Board member for more than 50 academic journals (e.g., Clinical Pharmacology
ongoing	and Therapeutics, Cardiovascular Drugs, Scientific Reports, Therapeutic Advances in
	Chronic Disease, Cephalalgia, Expert Opinion on Drug Safety, Frontiers in Artificial
	Intelligence, Drug Healthcare and Patient Safety, PLoS One, Renal Failure, and
	Pharmacoepidemiology and Drug Safety)
2018-	Review Board member for abstracts submitted to conferences organized by the
ongoing	International Society for Pharmacoepidemiology

MAJOR SCIENTIFIC COLLABORATIONS

I am currently collaborating on several granted research projects with Prof. Morten Andersen, the head of the Pharmacovigilance Research Center at the University of Copenhagen. At the Department of Drug Design and Pharmacology, I have strengthened my research collaborations with two key Research Clusters, "Metabolism and Inflammation Research Cluster" and "Personalized Medicine Research Cluster" led by Prof. Trond Ulven and Prof. Miriam Kolko (https://pubmed.ncbi.nlm.nih.gov/32510245/) with targeted research grants. Additionally, at the Department of Pharmacy, I have strengthened my collaboration with Assoc. Prof. Christine Erikstrup Hallgreen, the head of the Copenhagen Centre for Regulatory Science with a grant for developing an automatized infrastructure for retrieving data from regulatory documents. Finally, I have an ongoing EUfunded project with Assoc. Prof. Julien Kirchgesner from the University of Sorbonne for educational activities in Pharmacoepidemiology in Europe.

Other key research collaborators include:

- Prof. Christian Torp-Pedersen University of Copenhagen, Department of Public Health, Clinical Professor.
- Anders Peter Hviid Statens Serum Institut, Senior Researcher, Professor, Epidemiologisk Forskning / Afdeling for Epidemiologisk Forskning.

Research networks:

- >250 research collaborators affiliated with 160 different research institutions from 27 countries (source: Scopus).
- International Society of Pharmacoepidemiology Special Interest Group in geriatric pharmacoepidemiology.
- NorPEN a network of researchers with the purpose of facilitating research within the field of pharmacoepidemiology in the Nordic countries.

Consortia:

- Minerva consortium: a network of 35 research collaborators from several European countries involved in evidence generation from multi-countries pharmacoepidemiological studies

• INVITED SCIENTIFIC PRESENTATION AT NATIONAL AND INTERNATIONAL CONFERENCES

I have received more than 20 invitations for scientific presentations at National and International conferences. Selected invitations include:

- 1) National Conference of the Danish Society for Pharmacology (15th January 2020 in Odense, Denmark).
- 2) 18th World Congress of Basic and Clinical Pharmacology (August 2018 in Kyoto, Japan).
- 3) 2021 Mid-Year Meeting of the International Society for Pharmacoepidemiology (Online).
- 4) 84th Annual Meeting of the German Society for Experimental and Clinical Pharmacology and Toxicology (March 2018, Göttingen, Germany).
- 5) 39th National Meeting of the Italian Society of Pharmacology (November 2019 in Florence, Italy).
- 6) 2021 Annual Meeting of the International Society for Pharmacoepidemiology (Online).
- 7) 2022 Annual Meeting of the International Society for Pharmacoepidemiology (Bella Center, Copenhagen, Denmark).
- 8) 2022 Annual Meeting of NorPEN, Tampere, Finland.
- 9) EuroDURG 2023, Bologna, Italy
- 10) ISPE mid-year meeting 2023, Reykjavik, Island

EARLY ACHIEVEMENTS TRACK-RECORD

My early work (PhD) focused on investigating the association between molecular properties of beta-blockers and cardiorespiratory outcomes in patients with heart failure and chronic obstructive pulmonary disease using Danish administrative registers. An important achievement of this work was the discovery of a negative correlation between the use of beta-blockers with high beta-2 adrenoceptor selectivity and the risk of heart failure hospitalization due to the vicious negative link between bronchoconstriction, oxygen saturation, and heart failure contractility. The results of my PhD project have been pivotal to strengthening the recommendation in the European Society of Cardiology guidelines on the use of metoprolol rather than carvedilol in patients having both heart failure and chronic obstructive pulmonary (https://pubmed.ncbi.nlm.nih.gov/29327802/). On the paper published during my PhD was accompanied by an editorial paper in the official journal of the European Society of Cardiology and mentioned in other scientific journals such as ESC Heart Failure, BMJ, and, JACC: Heart Failure. I further investigated this topic using Italian and Danish administrative databases to unveil the association between molecular properties of betablocker and long-term outcomes focusing on clinically relevant subgroups identified using AI-driven models. This was a radically new approach for investigating the safety of beta-blockers as it used data on molecular properties from molecular pharmacology and cheminformatics in combination with data science methods while using administrative databases as data sources. During my postdoc at the University of Copenhagen, I focused on how to translate this approach to other data sources used in Pharmacovigilance such as spontaneous reports of adverse events while integrating artificial intelligence techniques from data science. The most important result was the preliminary discovery of being able to anticipate the detection of safety signals using the molecular properties of drugs such as affinity to off-target in spontaneous reporting databases for which I have pluriannual experience in management and analysis. The results of this research have also been published in in non-scientific journal aiming at lay communication of research findings such as BestPractice Nordic Online. Recently, to automatize the classification of identified safety signals as "not under evaluation by Regulatory Agency" among those identified with the new approach described above in collaboration with Ass. Prof. Christine Erikstrup Hallgreen, I started the development of an Artificial intelligence-guided infrastructure for real-time analytics of regulatory documents that received funds from the University of Copenhagen (please refer to the section on grants). My early scientific contribution is in line with my willingness of pursuing multidisciplinary research. I have always been a fervent partisan of the multidisciplinary approach in scientific investigations, and my current research interests are strongly driven by this motivation. This has been recognized at multiple levels, from the wide variety of nature of the journals I published into and the variety of journals soliciting me for papers (e.g., the use of machine learning in Pharmacoepidemiology by Frontiers in Pharmacology).

Awards as a student: 1) Best Communication Award, Italian Society of Pharmacology, Italy (in 2016); 2) Pharmacy student with the highest academic achievements in 2016, Second University of Naples, Italy; 3) best thesis in Pharmacy, Rotary international, Italy (2016).

CURRENT GRANTS

Project Title	Funding source (founding ID)	Amount (Euros)	Period	My Role
Seed4EU+	4EU+	50000€	September 2023 – September 2024	Principal investigator (10% of the working time)
Pharmacometrics-based clustering for Pharmacoepidemiological risk stratification in real-world evidence for drugs with a narrow therapeutic index: a data science approach.	Helsefonden (20-B-0059)	47039€	March 2021 – September 2021	Principal investigator (10% of the working time) I have employed a postdoc (Hiie Soeorg) for a mini-project that aims at using pharmacometrics models from the scientific literature for pharmacological substantiation of

				safety signals identified using Danish administrative registers as data sources for drugs with a narrow therapeutic index.
Nordic COllaborative HEalth REgister Network for Covid-19 Epidemiology (Nordic COHERENCE)	Nordforsk (105670)	970470€	February 2021 – February 2023	Work package leader (10% of the working time) I am involved in a multi-country project (e.g., Denmark, Norway, Sweden, and Scotland) as work package leader for a project aiming at evaluating risk factors for severe Covid-19 (disease leading to hospitalization, intensive care, or fatal outcome), identifying vulnerable populations, and characterizing the disease course, also on long-term sequelae among survivors of severe Covid-19. My work package aims at using administrative data sources and machine-learning techniques for identifying pharmacological treatments that may represent risk factors for severe Covid-19 infections.
Regulatory Science focusing on the development of an infrastructure for real- time analytics of regulatory documents	Novo Nordisk A/S	268000€	May 2021 - May 2023	Co-Principal Investigator (10% of the working time). I have employed a postdoc (Mohnish Pandey) for this project.
Targeting GPCRs for treatment of fibrosis	Novo Nordisk A/S	6000000 DKK	January 2022 – December 2024	Work package leader (10% of the working time)
Development of an integrated 4EU+ Pharmacoepidemiology educational program	4EU+	13312€	January 2022 – May 2022	Co-Principal Investigator (5% of the working time).

Peer-reviewed publications ordered by year of publication (2 publications have been omitted because errata of original articles)

First or Last authorship (*)	Title	Journal	Year	N.
*	Dong G, Kjærgaard NA, Shakibfar S, Sessa M. Ubrogepant and rimegepant: systematic review, meta- analysis, and meta-regression of clinical studies. Expert Opin Drug Saf 2023:1–12. https://doi.org/10.1080/14740338.2023.2177270.	Expert Opinion on Drug Safety	2023	78
*	Wang W, Battini V, Carnovale C, Noordam R, van Dijk KW, Kragholm KH, et al. A novel approach for pharmacological substantiation of safety signals using plasma concentrations of medication and	Pharmacological research	2023	78

and Drug Administration Adverse Event Reporting System. Expert Opin Drug Saf 2023:1–8. https://doi.org/10.1080/14740338.2023.2223958. Amiri D, Sessa M, Andersen M, Kolko M, Persistence and adtherence with Latanoprost: A Danish register- based cohort study in older patients with glaucoma. Acta Ophthalmol 2023. https://doi.org/10.1111/aos.15715. Al-Azzawi F, Mahmoud I, Haguinet F, Bate A, Sessa M. Developing an Artificial Intelligence-Guided Signal Detection in the Food and Drug Administration Adverse Event Reporting System (FAERS): A Proof-of- Concept Study Using Galcanezumab and Simulated Data. Drug Saf 2023. https://doi.org/10.1007/s40264- 023-01317-0. Breitenstein PS, Mahmoud I, Al-Azzawi F, Shakibfar S, Sessa M. A machine-learning guided method for predicting add-on and switch in secondary data sources: A case study on anti-seizure medications in Danish registries. Front Pharmacol 2022;13:954393. https://doi.org/10.3389/fphar.2022.954393. https://doi.	Г			1	
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