

Date of the CVA	11/02/2021
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Section A. PERSONAL DATA

Name and Surname	Maria Isabel Lucena Gonzalez		
DNI	24838959V	Age	64
Researcher's identification number	Researcher ID		
	Scopus Author ID	7005609503	
	ORCID	0000-0001-9586-4896	

* Obligatorio

A.1. Current professional situation

Institution	Malaga Institute of Biomedical Research (IBIMA) - University of Malaga- Virgen de la Victoria Hospital		
Dpt. / Centre			
Address	Boulevard Louis Pasteur, 29010, Málaga		
Phone	(0034) 636339426	Email	lucena@uma.es
Professional category	Full Professor of pharmacology. Clinical Pharmacology Service	Start date	2007
Keywords			

A.2. Academic education (Degrees, institutions, dates)

Bachelor/Master/PhD	University	Year
PhD MEDICINE AND SURGERY	UNIVERSIDAD DE GRANADA	1983

A.3. General quality indicators of scientific production

Section B. SUMMARY OF THE CURRICULUM

Professor M. Isabel Lucena is Director of the Clinical Pharmacology Service at the University Hospital of Malaga and Scientific coordinator of SCReN, Platform of Clinical research and clinical trials at IBIMA (2013-). Former Vice-director (2010-2013) and Scientific Director / Founder of IBIMA (Malaga Health Research Institute) (2013-2017). Director of the Pharmacology&Paediatrics Department (School of Medicine, University of Malaga). Belongs to CIBERehd, the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) and leads the PAIDI CTS-649 group. Co-IP of IBIMA Group on Hepatogastroenterology, Pharmacolog and Translational Clinical Pharmacology. Expert of the AEMPS (collaboration agreement 1999-) and the European Medicines Agency on liver safety. Member of the Executive Committee of the International Union of Basic and Clinical Pharmacology. Treasurer of the Clinil pharmacology division of IUPHAR. Rapporteur of CIOMS working Group on Drug-Induced Liver Injury (DILI). Member of the Reviewing board & organizer of the Post-Graduate Course on Lifestyle and Liver Diseases for the European Association for the Study of the Liver (EASL International Liver Congress (2016-). Co-director EASL Postgraduate Course (2021). She serves as projects' evaluator of national & international agencies and Invited speaker in international meetings. Funder and coordinator of the Spanish DILI Registry (www.spanishdili.uma.es) and of the Spanish Latin-American DILI Network; and of the Prospective European DILI Registry awarded by EASL. The main lines of research are epidemiological in DILI, causality, stratification of risk and mechanistics: genetics and immunophenotyping studies, other omics and clinical trials design in order to improve the mechanistic understanding of DILI and the development of novel biomarkers and their transfer into clinical practice. International collaborations: partners in the IMI Safer and Faster Evidence Based Translation consortium (SAFE-T, 2008-2015), the International Serious Adverse Event Consortium (iSAEC), IMI2 TRANSBIOLINE project (2019-), Eurostars Programme: Novel Combo Assay for Early Detection of DILI (E114589-LiverAce. 2021-) and leading the COST Action 17112 Prospective European Drug-Induced Liver Injury Network

(<https://proeurodilinet.eu>). Collaboration with Prof Kaplowitz (South California U), Susuki at Duke U, Aithal (Nottingham) and Chen M (National Centre for Toxicological Research-FDA). This work has allowed us a leading position in international DILI research. She has received continuous competitive funding. She published over 20 book chapters and more than 300 articles in peer-review journals. She has an H-index of 44 and 6444 citations. 15 publications were cited more than 100 times and 37 original articles received more than 50 citations. She has directed 25 PhD thesis included 3 Internacional thesis, 5 Extraordinary awards and 1 doctoral thesis co-tutelle with the University of Maastricht, Germany (defense 12thFeb.21). Human resources through competitive convocatories: 2 technicians Garantia Juvenil (2016-2019), 2 Río Ortega (2017 & 2019), 1 clinical pharmacology specialist, 2 postdoctorals for the Platform of Clinical research and clinical trials, Contrato i-PFIS IF118/00047.

Section C. MOST RELEVANT MERITS (ordered by typology)

C.1. Publications

AC: Autor de correspondencia; (nº x / nº y): posición firma solicitante / total autores

- 1 Scientific paper.** CAMILLA STEPHENS; MERCEDES ROBLES-DIAZ; INMACULADA MEDINA-CALIZ; et al; M ISABEL LUCENA (AC); RAÚL J ANDRADE.(25/26). 2021. Comprehensive analysis and further insights gained from the long-term experience of the Spanish DILI Registry.Journal of Hepatology (D1: 2/88) CORRESPONDING AUTHOR. ELSEVIER. ISSN 0168-8278.
- 2 Scientific paper.** FERNANDO BESSONE; NELIA HERNANDEZ; MANUEL MENDIZABAL; et al; M ISABEL LUCENA (AC); RAUL J ANDRADE.(23/24). 2021. Serious liver injury induced by Nimesulide: an international collaboration study reporting 57 cases.Archives of Toxicology (D1: 9/92) ACCEPTED FOR PUBLICATION - SHARE SENIOR AUTHORSHIP. ISSN 0340-5761.
- 3 Scientific paper.** WEERSINK RA; ALVAREZ-ALVAREZ I; MEDINA-CÁLIZ I; et al; LUCENA MI (AC); ANDRADE RJ.(15/16). 2020. Clinical characteristics and outcome of drug-induced liver injury in the older patients: from the young-old to the oldest-old.Clinical Pharmacology & Therapeutics (D1: 16/271) CORRESPONDING AUTHOR. WILEY. ISSN 0009-9236.
- 4 Scientific paper.** RIVERA P; VARGAS A; PASTOR A; et al; LUCENA MI; SUÁREZ J.(12/15). 2020. Differential hepatoprotective role of the cannabinoid CB1 and CB2 receptors in paracetamol-induced liver injury.British Journal of Pharmacology (D1: 9/270). WILEY. 177-14, pp.3309-3326. ISSN 0007-1188.
- 5 Scientific paper.** ZOUBEK MIGUEL; LUCENA GONZÁLEZ MARÍA ISABEL (AC); ANDRADE RAÚL; STEPHENS CAMILLA. (2/4). 2020. Systematic review: Ibuprofen-induced liver injury.Alimentary Pharmacology & Therapeutics (D1: 11/271; CORRESPONDING AUTHOR). WILEY. 51-6, pp.603-611. ISSN 0269-2813.
- 6 Scientific paper.** PAOLA NICOLETTI; GURUPRASAD AITHAL; THOMAS CHAMBERLAIN; et al; M. ISABEL LUCENA; AND ANN DALY.(11/19). 2019. Drug-induced injury due to flucloxacillin: relevance of multiple HLA alleles.Clinical Pharmacology & Therapeutics (D1: 16/270). WILEY. 106-1, pp.245-253. ISSN 0009-9236.
- 7 Scientific paper.** Medina-Caliz I; Garcia-Cortes M; Gonzalez-Jimenez A; et al; Lucena MI (AC); Andrade RJ. (24/25). 2018. Herbal and Dietary Supplement-induced Liver Injuries in the Spanish DILI Registry Clinical Gastroenterology and Hepatology (D1, 8 of 84; CORRESPONDING AUTHOR). ELSEVIER SCIENCE INC. 16-9, pp.1495-1502. ISSN 1542-3565.
- 8 Scientific paper.** Zoubek ME; Gonzalez-Jimenez A; Medina-Cáliz I; et al; Lucena MI (AC); Andrade RJ. (10/12). 2018. High Prevalence of Ibuprofen Drug-Induced Liver Injury in Spanish and Latin-American Registries.Clin. Gastroenterol. Hepatol. (D1, 8 of 84; CORRESPONDING AUTHOR). ELSEVIER SCIENCE INC. 16-2, pp.292-294. ISSN 1542-3565.
- 9 Scientific paper.** Barbier-Torres L; Iruzubieta P; Fernández-Ramos D; et al; Lucena MI; Martínez-Chantar ML.(21/29). 2017. The mitochondrial negative regulator MCJ is a therapeutic target for acetaminophen-induced liver injury Nature Communications (D1: 3 of 64). NATURE PUBLISHING GROUP. 8-1, pp.2068-2079. ISSN 2041-1723.

- 10 **Scientific paper.** Inmaculada Medina-Caliz; MERCEDES ROBLES-DIAZ; BEATRIZ GARCIA-MUÑOZ; et al; M ISABEL LUCENA (AC); RAUL J ANDRADE. (29/30). 2016. Definition and risk factors for chronicity following acute idiosyncratic drug-induced liver injury *Journal of Hepatology* (D1 : 3 of 84). (Position 29 of 30, corresponding author). 65-3, pp.532-542. ISSN 0168-8278.
- 11 **Scientific paper.** GONZALEZ-JIMENEZ A; MCEUEN K; CHEN M; et al; LUCENA MI (AC); ANDRADE RJ.(11/13). 2019. The influence of drug properties and host factors on delayed onset of symptoms in Drug-Induced Liver Injury.*Liver international* (Q1: 19/88; CORRESPONDING AUTHOR). WILEY. 39-2, pp.401-410. ISSN 1478-3223.
- 12 **Review.** HAO NIU; JUDITH SANABRIA-CABRERA; ISMAEL ALVAREZ-ALVAREZ; et al; M ISABEL LUCENA (AC). (9/9). 2021. Prevention and management of idiosyncratic drug-induced liver injury: Systematic review and meta-analysis of randomised clinical trials *Pharmacological Research* (D1: 19/271) CORRESPONDING AUTHOR. ACADEMIC PRESS LTD- ELSEVIER SCIENCE LTD. 164, pp.105404. ISSN 1043-6618.
- 13 **Review.** M ISABEL LUCENA (AC); JUDITH SANABRIA; MIREN GARCIA-CORTES; CAMILLA STEPHENS; RAUL J ANDRADE.(1/5). 2020. Review. Drug-Induced Liver Injury in older people.*Lancet Gastroenterology & Hepatology* (D1: 5/88). CORRESPONDING AUTHOR. ELSEVIER INC. 5-9, pp.862-874.
- 14 **Review.** ANDRADE RJ; CHALASANI N; BJÖRNSSON ES; et al; LUCENA MI (AC); AITHAL GP.(9/11). 2019. Review. Drug-induced liver injury.*Nature Reviews Disease Primers* (D1: 4/165; CORRESPONDING AUTHOR). NATURE PUBLISHING GROUP. 5-1, pp.58-58. ISSN 2056-676X.
- 15 **Scientific-technical report.** 2019. EASL Clinical Practice Guideline: Occupational liver diseases.*Journal of Hepatology* (D1: 2/88, Panel member). ELSEVIER SCIENCE BV. 71-5, pp.1022-1037. ISSN 0168-8278.

C.2. Participation in R&D and Innovation projects

- 1 IMI2- Translational Safety Biomarker Pipeline (TransBioLine): Enabling development and implementation of novel safety biomarkers in clinical trials and diagnosis of disease. IP MI LUCENA. (Universidad de Málaga). 01/02/2019-31/01/2024. 246.452,5 €. Principal investigator.
- 2 PT20-00127, Platform for the conducting of clinical studies and clinical trials. Carlos III Health Institute. PI M Isabel Lucena. (University Hospital Virgen la Victoria). 01/01/2021-31/12/2023. 302.000 €. Principal investigator.
- 3 PY18-3364, Exosomes, the immune response and its modulation by the GUT microbiota in the identification of mechanistic and prognostic hepatotoxicity biomarkers Junta de Andalucía. Convocatoría PAIDI 2018. Ayudas a proyectos de I+D+I Programa Operativo FEDER 2014-2020.. PI. M^a Isabel Lucena. (University of Malaga). 2020-2023. 140.352 €. Principal investigator.
- 4 PI19/00883, Analysis of immunoregulatory lymphocyte populations in hepatotoxicity using mass cytometry (CyTOF): determining the drug-induced liver injury (DILI) immunological fingerprint Carlos III Health Institute. IP M^a Isabel Lucena. (University Hospital Virgen de la Victoria). 01/01/2020-31/12/2022. 93.170 €. Principal investigator.
- 5 COST Action CA17112 - Prospective European Drug-Induced Liver Injury Network (PRO-EURO DILI NET) COST ASSOCIATION AISBL. SCIENTIFIC COORDINATOR MI LUCENA. (IBIMA-UMA). 01/11/2018-15/10/2022. 400.000 €.
- 6 UMA18-FEDERJA-194, The impact of extracellular vesicles of bacterial origin on immune system modulation and development of non-alcoholic steatohepatitis and Drug-Induced Liver Injury. Proyectos I+D+I - Programa Operativo FEDER Andalucía 2014-2020 University of Malaga. Proyectos I+D+I - Programa Operativo FEDER Andalucía 2014-2020. IP M^a Isabel Lucena. (University of Malaga). 01/11/2019-31/10/2021. 39.250 €. Principal investigator.
- 7 PT17/0017/0020, Platform for the conducting of clinical studies and clinical trials. PT17/0017/0020 Carlos III Health Institute. PI M Isabel Lucena. (University Hospital Virgen la Victoria). 01/01/2018-31/12/2020. 179.300 €. Principal investigator.

- 8 PI16/01748, Analysis of the adaptive immune response and the receptors involved in the immune check point in the development and severity of hepatotoxicity. Influence of the intestinal microbiota. Instituto de Salud Carlos III. IP. (HUVV-UMA). 2017-2019. 151.915 €.
- 9 PI-0274-2016, Identification of diagnostic and pronostic Biomarkers in Hepatotoxicity. Comparative study between healthy controls and acute Hepatitis induced by different etiologies. Andalusian Health Service (SAS). Regional Ministry of Health. Co-PI. (Hospital Clínico Universitario Virgen la Victoria). 2017-2019. 31.291 €. Team member.
- 10 EASL Registry Research Grants Progame. Title: Creation of a European Prospective Drug-Induced Liver Injury Registry (Pro-Euro-DILI Registry). European Association for the Study of the Liver. Co-PI. (Hospital Clínico Universitario Virgen la Victoria). 2014-2015. 50.000 €.
- 11 E!114589 – LiverAce, Novel Combo Assay for Early Detection of Drug Induced Liver Injury (DILI). Programme: Eurostars Centro para el Desarrollo Tecnológico Industrial; FFG Österreichische Forschungsförderungsgesellschaft mbH. Eurostars. PIs: Dr Maribel Lucena Dr Raúl Andrade Bellido (Spain). (IBIMA-UMA). From 2021. 1.417.892 €. Principal investigator.

C.3. Participation in R&D and Innovation contracts

- 1 Group of Drug-Induced Liver Diseases CIBER ENFERMEDADES HEPATICAS Y DIGESTIVAS (CIBEREHD). PI Raúl J. Andrade. (Hospital Clínico Universitario Virgen la Victoria). 01/01/2021-01/01/2022. 50.000 €.
- 2 Collaboration agreement between the Spanish Agency of Medicines & the University of Malaga for the study of the SPANISH DILI Registry. Universidad de Málaga; Agencia Española de Medicamentos y Productos Sanitarios. PI MI LUCENA. 01/10/2020-01/10/2022. 60.500 €.
- 3 Collaboration Agreement between the Nottingham University Hospitals NHS TRUST, the University of Nottingham, FIMABIS, IBIMA & PFIZER. Transfer of the Data and Material from "Pro-Euro-DILI Registry" and "NASH" to Pfizer. Project: Assessment of novel DILI biomarkers in retrospective Pro Euro DILI cohort. Pfizer, S.A.. PI Raúl J. Andrade MI Lucena. 07/05/2020-30/11/2020. 19.415,31 €.
- 4 Collaboration agreement between the Spanish Agency of Medicines & the University of Málaga for the study of the SPANISH DILI Registry. Universidad de Málaga; Agencia Española de Medicamentos y Productos Sanitarios. IP. 01/10/2018-01/10/2020. 60.500 €.
- 5 Collaboration agreement between the Spanish Medicine Agency and the University of Malaga, through the Pharmacology & Medicine department for the study of Drug-Induced Liver Injury Universidad de Málaga; Agencia Española de Medicamentos y Productos Sanitarios. IP. 01/04/2016-10/12/2017. 50.820 €.

C.4. Patents

Aida Ortega Alonso; Raúl J. Andrade; M. Isabel Lucena; Andres Gonzalez Jimenez; Aurelie Papineau; Mercedes Robles-Diaz. SE-1185-16. SE-1185-16. Diseño Aplicación móvil eDILI para uso profesional Spain. 21/12/2016. SERVICIO ANDALUZ DE SALUD; UNIVERSIDAD DE MÁLAGA.