

Date of the CVA	13/02/2020
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Section A. PERSONAL DATA

Name and Surname	Maria Isabel Lucena Gonzalez		
DNI	24838959V	Age	63
Researcher's identification number	Researcher ID		
	Scopus Author ID	7005609503	
	ORCID	0000-0001-9586-4896	

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
UNESCO spec. code			
Keywords			

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

Bachelor/Master/PhD	University	Year
MEDICAL SPECIALIST ON PHARMACOLOGY	MINISTERIO DE SANIDAD Y CONSUMO	1984
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- jul 2013) and Scientific Director of IBIMA (Malaga Health Research Institute) (2013-2017). 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 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. 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-). 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 the recently set-up Prospective European DILI Registry awarded by EASL.

The main lines of research are epidemiological, risk factors and patient stratification, genetic and immunophenotyping studies 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), as well as joint research projects with Prof Kaplowitz (South California University), Prof Ayako at Duke University and also with the National Centre for Toxicological Research (FDA). We are partner of the TRANSBIOLINE IMI 2018 project, and scientific coordinator the COST Action 17112

Prospective European Drug-Induced Liver Injury Network (<https://proeurodilinet.eu>) led by our group. This work has allowed us a leading position in international DILI research.

She has received continuous competitive funding from national public and private organisms. She is member of the editorial board of: *Hepatology* (2012-2016) (D1) and *Frontiers in Pharmacology* (Q1). She published over 20 book chapters and more than 200 articles in peer-review journals. She has an H-index of 42 and 5827 citations by 3288 documents. 14 publications were cited more than 100 times and 33 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 AAachen, Germany in progress. Human resources through competitive convocatories: 2 technicians *Garantía Juvenil* (2016-2019), 2 *Río Ortega* (2017 & 2019), 1 clinical pharmacology specialist, 1 early stage and 1 postdoctoral for the SCReN Platform of Clinical research and clinical trials, *Contrato i-PFIS IFI18/00047 Doctorados IIS-empresa en Ciencias y Tecnologías de la Salud*.

Section C. MOST RELEVANT MERITS (ordered by typology)

C.1. Publications

- 1 Scientific paper.** ZOUBEK MIGUEL; et al. (4/2). 2020. Systematic review: Ibuprofen-induced liver injury. *Alimentary Pharmacology & Therapeutics* (D1: 10/267; CORRESPONDING AUTHOR) IN PRESS. WILEY. ISSN 0269-2813.
- 2 Scientific paper.** CIRULLI ET; et al. (22/10). 2019. A Missense Variant in PTPN22 is a Risk Factor for Drug-induced Liver Injury. *Gastroenterology* (D1: 2/84). W B SAUNDERS CO-ELSEVIER INC. 156-6, pp.1707-1716. ISSN 0016-5085.
- 3 Scientific paper.** TORRES S; et al. (18/12). 2019. Endoplasmic Reticulum Stress-Induced Upregulation of STARD1 Promotes Acetaminophen-Induced Acute Liver Failure. *Gastroenterology* (D1: 2/84). W B SAUNDERS CO-ELSEVIER INC. 157-2, pp.552-568. ISSN 0016-5085.
- 4 Scientific paper.** Medina-Caliz I; et al. (25/24). 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.
- 5 Scientific paper.** Zoubek ME; et al. (12/10). 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.
- 6 Scientific paper.** Nicoletti P; et al. (44/28). 2017. Association of Liver Injury From Specific Drugs, or Groups of Drugs, With Polymorphisms in HLA and Other Genes in a Genome-Wide Association Study *Gastroenterology* (D1, 1 of 80). W B SAUNDERS CO-ELSEVIER INC. 152-5, pp.915-917. ISSN 0016-5085.
- 7 Scientific paper.** Barbier-Torres L; et al. (29/21). 2017. The mitochondrial negative regulator MCJ is a therapeutic target for acetaminophen-induced liver injury *Nature Communications* (D1: 3 of 64). NATURE PUBLISHING GROUP. 6, pp.2068-2079. ISSN 2041-1723.
- 8 Scientific paper.** Inmaculada Medina-Caliz; et al. (30/29). 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.
- 9 Scientific paper.** Robles-Diaz, M; et al. (20/19). 2015. Distinct phenotype of hepatotoxicity associated with illicit use of anabolic androgenic steroids *Alimentary Pharmacology & Therapeutics* (D1: 10/267 CORRESPONDING AUTHOR). WILEY. 41-1, pp.116-125. ISSN 0269-2813.
- 10 Scientific paper.** Chen M; et al. (5/5). 2015. REVIEW. Drug-Induced liver injury: interactions between drug properties and host factors *Journal of Hepatology* (D1: 5 of 79). (Position 5 of 5, senior). 63-2, pp.503-514. ISSN 0168-8278.
- 11 Scientific paper.** PAOLA NICOLETTI; et al. (19/11). 2019. Drug-induced injury due to flucloxacillin: relevance of multiple HLA alleles. *Clinical Pharmacology & Therapeutics* (D1: 15/267). WILEY. 106-1, pp.245-253. ISSN 0009-9236.

- 12 **Scientific paper.** GONZALEZ-JIMENEZ A; et al. (13/11). 2019. The influence of drug properties and host factors on delayed onset of symptoms in Drug-Induced Liver Injury. *Liver international* (Q1: 16/84; CORRESPONDING AUTHOR). WILEY. 39-2, pp.401-410. ISSN 1478-3223.
- 13 **Scientific paper.** Pär Hallberg; et al. 2017. Genetic variants associated with antithyroid drug-induced agranulocytosis: a genome-wide association study in a European population. *Lancet Diabetes & Endocrinology* (D1, 2 of 133). (Position 7 of 14). ISSN 2213-8587.
- 14 **Scientific paper.** Stephens C; et al. (12/11). 2016. Killer Immunoglobulin-like receptor profiles are not associated with risk of amoxicillin-clavulanate-induced liver injury in Spanish patients *Frontiers in Pharmacology* (Q1: 33 of 255). (Position 11 of 12, corresponding author). 7, pp.280-280. ISSN 1663-9812.
- 15 **Scientific paper.** Robles-Diaz M.; et al. (17/16). 2015. The value of serum aspartate aminotransferase and gamma-glutamyl transpeptidase as biomarkers in hepatotoxicity *Liver International* (Q1: 16/84; CORRESPONDING AUTHOR). WILEY. 35-11, pp.2474-2482. ISSN 1478-3223.
- 16 **Review.** ANDRADE RJ; et al. (11/9). 2019. Review. Drug-induced liver injury. *Nature Reviews Disease Primers* (D1: 4/160; CORRESPONDING AUTHOR). NATURE PUBLISHING GROUP. 5-1, pp.58-58. ISSN 2056-676X.
- 17 **Scientific-technical report.** 2019. EASL Clinical Practice Guideline: Occupational liver diseases. *Journal of Hepatology* (D1: 3/84, 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). 2019-2023. Principal investigator.
- 2 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.
- 3 IF18/00047, Contrato i-PFIS: doctorados IIS-empresa en ciencias y tecnologías de la salud. Convocatoria 2018 de la Acción Estratégica en Salud 2013-2016 Instituto de Salud Carlos III. IP MI LUCENA. (Universidad de Málaga). 01/01/2019-31/12/2022. 82.400 €. Principal investigator.
- 4 COST Action CA17112 - Prospective European Drug-Induced Liver Injury Network (PRO-EURO DILI NET) COST ASSOCIATION AISBL. SCIENTIFIC COORDINATOR MI LUCENA. (IBIMA-UMA). 2018-2022.
- 5 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 Universidad de Málaga. 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.
- 6 Contrato de personal Técnico de Apoyo a la I+D+i financiados por el programa operativo de empleo juvenil Cecilio Porras. (Universidad de Málaga). 29/01/2018-25/07/2019.
- 7 RESEARCH PLAN 2018. University of Málaga (vicerrector of scientific research) grant for the setting up of the "TRANSBIOLINE REGISTRY" Universidad de Málaga. M^a Isabel Lucena. (University of Malaga). 23/05/2018-22/05/2019. 4.000 €. 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 prognostic 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 €. Co-ordinator.

- 10 Contrato de personal Técnico de Apoyo a la I+D+i financiados por el programa operativo de empleo juvenil Marta Quiros. (Universidad de Málaga). 01/05/2017-01/05/2018.
- 11 SAFE-T Safer and faster Evidence Based Translation. SAFE-T INTERFACE EUROPE Innovative Medicines Initiative Grant Agreement number 523 705; Innovative Medicines Initiative. IP Raúl J. Andrade. (Universidad de Málaga). 01/01/2011-14/06/2015. 149.400 €.
- 12 EASL Registry Research Grants Programme. 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 €.
- 13 RESEARCH PLAN. University of Málaga (vicerrector of scientific research) grant for the organization of the "I Working groups meeting of the COST". Universidad de Málaga. M^a Isabel Lucena IP. (University of Malaga). From 2019. 4.000 €. Principal investigator.
- 14 Contrato Río Ortega de la Acción Estratégica en Salud 2013-2016. Convocatoria 2017. CM17/00243 Instituto de Salud Carlos III. Judith Sanabria Cabrera. (Hospital Clínico Universitario Virgen la Victoria). From 01/04/2018. Principal investigator.

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

- 1 Grupo de hepatopatías asociadas a medicamentos CIBER ENFERMEDADES HEPATICAS Y DIGESTIVAS (CIBEREHD). IP Colaborador. (Hospital Clínico Universitario Virgen la Victoria). 01/01/2019-01/01/2020. 50.000 €.
- 2 Predoctoral contract. PT13/0002/0020: Clinical Research and Clinical Trial Units (UICECs). Carlos III Health Institute. Jessica Gasca Bellido. 01/02/2018-P8M25D.
- 3 Postdoctoral contract. PT13/0002/0020: Clinical Research and Clinical Trial Units (UICECs). Carlos III Health Institute. Rocío SanJuan. 01/12/2017-P2Y30D.
- 4 Contract for a specialist in clinical pharmacology. PT13/0002/0020: Clinical Research and Clinical Trial Units (UICECs). Carlos III Health Institute. Judith Sanabria Cabrera. 01/01/2017-P1Y3M.
- 5 Platform for the conducting of clinical studies and clinical trials. PT17/0017/0020 Carlos III Health Institute. PI. 2017-P3Y. 179.300 €.
- 6 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-P1Y8M10D. 50.820 €.
- 7 RESEARCH PLAN 2015. University of Málaga (vicerrector of scientific research) grant for the setting-up of thematic networks: "Hepatotoxicity, Biomarkers study, Samples collection". University of Malaga. Andrade RJ. 2015-P1Y. 4.000 €.
- 8 International Consortium on Drug Hypersensitivity (IDILIC) ("Network") and development of Spanish-Latin DILI Network. Título: Genome wide analysis and sequencing on drugs-induced liver injury. SAE CONSORTIUM LTD. MI Lucena. 2010-P3Y. 227.000 €.

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.