CURRICULUM VITAE ABREVIADO (CVA)

Part A. PERSONAL INFORMATION

First name	Carolina		
Family name	Sousa Martín		

A.1. Current position

Position	Full Professor
Initial date	2012
Institution	University of Seville
Department/Center	Department of Microbiology and Parasitology/ Faculty of Pharmacy
Country	Spain
Key words	gastrointestinal diseases, immunogenic peptides, celiac disease, gluten

A.2. Previous positions (research activity interuptions, indicate total months)

Period	Position/Institution/Country/Interruption cause
2002-2012	Titular Professor / University of Seville /Spain
1996-2002	Associate Professor / University of Seville/Spain

A.3. Education

PhD, Licensed, Graduate	University/Country	Year
Ph.D. in Pharmacy	University of Seville/Spain	1992
Graduate in Pharmacy	University of Seville/Spain	1986

Part B. CV SUMMARY

My research activity is reflected in a total of 5 six-year periods in research and 1 in technology transfer. I have participated in 43 research projects (PI in 22 of them), 20 contracts with companies (PI in 17 of them), and 17 clinical trials (national and international). These projects and clinical trials have resulted in over 100 scientific publications, 200 scientific contributions at national and international conferences, 4 internationally extended and licensed patents, and technology transfer agreements with various government agencies and companies in the technological, agri-food, and health sectors. The techniques developed have been included in national/international protocols and clinical guidelines. I have supervised a total of 16 Doctoral Theses, 14 in academic research and 2 in industrial research. All PhD candidates have published between 2 and 10 articles indexed in JCR during the completion of their doctoral theses, with 80% of the articles in the first quartile. They have participated i research projects, and have undertaken stays in internationally renowned research centers, each lasting at least one year. Some of these stays have been financially supported by EMBO fellowship grants. Additionally, some of the doctoral candidates are co-authors of patents that have been internationally extended and licensed to companies.

The research group of which I am the principal investigator is a global leader in gastrointestinal pathologies related to adverse reactions to food. I established a highly interdisciplinary group that

allowed me to collaborate with national and international companies, such as Active Motif (USA), Biomedal S.L. (Spain), and Hygiena Topco LLC (USA), among others, achieving several significant milestones:

- Development of immunological methods capable of quantifying the toxic potential of gluten in food/raw materials intended for patients with these pathologies. With the trademark GlutenTox®, these analytical techniques have been commercialized by Biomedal S.L. (Spain) and Hygiena Topco LLC (USA). The developed and marketed products include Glutentox Sticks, Glutentox Sticks Plus, Glutentox Home, Glutentox Elisa Competitive, and Glutentox Elisa Sandwich. One of the products, GlutenTox® Pro, has been the best-selling product in its category in the USA. Following Hygiena Topco LLC's acquisition of this business unit from Biomedal S.L., human resources in the subsidiary Hygiena Diagnóstica España increased by 25%, with distributors in more than 100 countries.
- Study of the immunotoxic potential of oats for the subsequent development of methods for selecting safe varieties for celiacs and associated pathologies. The techniques developed were patented (P 201001632/ ES 2385463 A1/ PCT ES2011 000378), leading to changes in food safety legislation at both national and international levels. Once patented, this work was published in the prestigious journal *Gut* and was selected as being among the top 2% of the best scientific articles of the month by *Faculty of 1000* in the category of Medicine and Biology.
- Development of a non-invasive biomarker for the direct determination of gluten intake in stool and urine samples to control intestinal and extraintestinal symptoms and prevent the development of oncological diseases. These techniques were patented (P201001633/ ES2385455B2/ PCT ES2011 000379 and P201400569/ ES2556177B1/ PCT ES2015 070536) and later published in an internationally renowned journal. The products developed with the trademark VYDAL In Vitro Diagnostics® are divided into professional (IVD) and home-use (GlutenDetect) lines. These methods have been included in national and international clinical protocols and guidelines, such as the "Protocol for the early diagnosis of celiac disease" (2008), the American College of Gastroenterology guidelines (2023), and the Guidelines for best practices in monitoring established coeliac disease in adult patients (2023). They are marketed to hospitals, primary care centers, pharmacies, laboratories, etc. These biomarkers obviate biopsies, reducing costs to the National Health System. Additionally, they are being used by companies such as ImmunogenX (USA) for therapy development.

The research I have conducted has led to collaborations with some of the world's top universities, such as Harvard and Stanford. Recently, the declaration on society's gaps and opportunities for the study of celiac disease and associated pathologies, published in *Nature Reviews Gastroenterology & Hepatology*, presents these scientific advances as one of the latest milestones in the history of allergen-related pathologies.

I have received several international awards, including those from the European Society for Paediatric Gastroenterology Hepatology and Nutrition and the Federation of European Nutrition Societies. At the national level, noteworthy awards include the Losada Villasante Excellence in Innovation and the Ibero-American Academy of Pharmacy, among others.

Part C. RELEVANT MERITS

C.1. Publications

1 Mendia I., Segura V., Ruiz-Carnicer Á., et al., (AC: **Sousa C**); (12/12). 2023. Rapid anti-tTG-IgA screening test for early diagnosis of celiac disease in pediatric populations. Nutrients. 15(23):4926. https://doi.org/10.3390/nu15234926. JCR: 5,9 – Q1.

2 Palanski BA., Weng N., Zhang L., et al., (AC: Elias JE); (8/11). 2022. An efficient urine peptidomics workflow identifies chemically defined dietary gluten peptides from patients with celiac disease. Nature Communications. 13 (1), 888.

https://doi.org/10.1038/s41467-022-28353-1. JCR: 16,6 - D1. Citations: 12 (Scopus)/ 13 (Dimensions).

3 Fernández-Bañares F., Beltrán B., Salas A., et al., (AC: Fernández-Bañares F); (17/17). 2021. Persistent villous atrophy in de novo adult patients with celiac disease and strict control of gluten-free diet adherence: a multicenter prospective study (CADER Study).The American Journal of Gastroenterology. 116 (5), 1036-1043. https://doi.org/10.14309/ajg.0000000000001139. JCR: 12,045 - D1. Citations: 24 (Scopus)/ 35 (Dimensions).

4 Silvester JA., Comino I., Kelly CP., **Sousa C.,** Duerksen DR., DOGGIE BAG Study Group. (AC: Silvester JA); (4/6). 2019. Most patients with celiac disease on gluten-free diets consume measurable amounts of gluten. Gastroenterology. 158 (5), 1497-1499.e1. https://doi.org/10.1053/j.gastro.2019.12.016. JCR: 17,373 - D1. Citations: 53 (Scopus)/ 64 (Dimensions).

5 Comino I., Segura V., Ortigosa L., et al., (AC: **Sousa C**); (15/15). 2019. Prospective longitudinal study: use of faecal gluten immunogenic peptides to monitor children diagnosed with coeliac disease during transition to a gluten-free diet. Alimentary Pharmacology & Therapeutics. 49 (12), 1484-1492. https://doi.org/10.1111/apt.15277. JCR: 7,515 - D1. Citations: 40 (Scopus)/ 47 (Dimensions).

6 Moreno ML., Cebolla Á., Muñoz-Suano A., et al., (AC: **Sousa C**); (9/9). 2017. Detection of gluten immunogenic peptides in the urine of patients with coeliac disease reveals transgressions in the gluten-free diet and incomplete mucosal healing. Gut. 66 (2), 250-257. https://doi.org/10.1136/gutjnl-2015-310148. JCR: 16,658 - D1. Citations: 207 (Scopus)/223 (Dimensions).

7 Comino I., Fernández-Bañares F., Esteve M., et al., (AC: **Sousa C**); (40/40). 2016. Fecal gluten peptides reveal limitations of serological tests and food questionnaires for monitoring gluten-free diet in celiac disease patients. The American Journal of Gastroenterology. 111 (10), 1456-1465. https://doi.org/10.1038/ajg.2016.439. JCR: 9,566 - D1. Citations: 143 (Scopus)/157 (Dimensions).

8 Moreno Mde L., Muñoz-Suano A., López-Casado MÁ., Torres MI., Sousa C., Cebolla Á. (AC: **Sousa C**); (5/6). Selective capture of most celiac immunogenic peptides from hydrolyzed gluten proteins. Food Chemistry. 2016 205, 36-42. https://doi.org/10.1016/j.foodchem.2016.02.066. JCR: 4,529 - D1. Citations: 25 (Scopus)/23 (Dimensions).

9 Comino I., Real A., Vivas S., et al., (AC: **Sousa C.**); (10/10). 2012. Monitoring of glutenfree diet compliance in celiac patients by assessment of gliadin 33-mer equivalent epitopes in feces. The American Journal Clinical Nutrition. 3:670-677. https://doi.org/10.3945/ajcn.111.026708. JCR: 6,504 - D1. Citations: 138 (Scopus)/ 139 (Dimensions).

10 Comino I., Real A., de Lorenzo L., et al., (AC: **Sousa C**); (10/10). 2011. Diversity in oat potential immunogenicity: basis for the selection of oat varieties with no toxicity in coeliac disease. Gut. 60:915-920. https://doi.org/10.1136/gut.2010.225268. JCR: 10,111 - D1. Citations: 124 (Scopus)/ 122 (Dimensions).

C.2. Research projects.

1 Nuevos métodos de alta precisión para el diagnóstico de intolerancia al gluten (CELISIN). RTC2019-006806-1. Ministerio de Ciencia e Innovación. **PI: C. Sousa**. 01/02/2020-30/06/2023.

2 Nutripeptidoma del líquido amniótico y sus implicaciones en las patologías relacionadas con el gluten. US-15332. Junta de Andalucía (Consejería de Economía y Conocimiento). **PI: C. Sousa.** 01/01/2020-30/04/2022.

3 Metabolómica del gluten: caracterización y estudio de patrones de péptidos inmunogénicos del gluten excretados en orina de pacientes con patologías relacionadas con el gluten (METAGIP).

SAF2017-83700-R. Ministerio de Economía y Competitividad. **PI: C. Sousa.** 01/01/2018-30/09/2021.

4 Desarrollo de una plataforma universal para el diseño y validación rápida de inmunoensayos de flujo lateral (UNIVERTEST). RTC-2016-5441-1. Ministerio de Economía y Competitividad. **PI: Carolina Sousa.** 01/09/2016-30/04/2019.

5 Métodos rápidos de análisis de péptidos inmunogénicos alimenticios en orina (URINETEST). RTC-2016-5452-1. Ministerio de Economía y Competitividad. **PI: C. Sousa.** 01/09/2016-30/04/2019.

6 Caracterización de las proteínas inmunotóxicas de la avena mediante análisis inmunológicos: obtención de nuevas variedades no tóxicas para ser consumidas por los enfermos celíacos. P12-AGR-1762. Junta de Andalucía (Consejería de Innovación, Ciencia y Empresas). **PI: C. Sousa.** 30/01/2014-01/02/2018.

7 Métodos para el diagnóstico confirmatorio de la enfermedad celíaca y el seguimiento de dieta sin gluten. RTC-2014-2401-1. Ministerio de Economía y Competitividad. **PI: C. Sousa.** 01/01/2014-31/12/2017.

8 Determinación de la Inmunotoxicidad de Variedades de Trigo Modificadas Genéticamente para su Aplicación Seguridad Alimentaria en el Colectivo Celiaco. AGL2013-48946-C3-2-R. Ministerio de Economía y Competitividad. **PI: C. Sousa.** 01/01/2014- 31/12/2016.

9 Métodos de para verificación del cumplimiento de la dieta en casos de intolerancias alimentarias mediante la detección de marcadores serológicos y/o de péptidos alimenticios. DELIAC. IPT-2011-0952-900000. Ministerio de Ciencia e Innovación. **PI: C. Sousa**. 05/05/2011- 28/02/2014.

10 La avena como cereal del alto valor añadido para celíacos: obtención de variedades no tóxicas y desarollo de nuevos productos funcionales. IPT-2011-1321-010000. Ministerio de Ciencia e Innovación. **PI: C. Sousa**. 05/05/2011- 31/12/2014.

C.3. Contracts, technological or transfer merits.

Contracts:

1 Desarrollo de anticuerpos recombinantes de aplicación en el diagnóstico, monitorización y terapia de la enfermedad celíaca. **PI: C. Sousa**. 15/02/2022-15/03/2024.

2 Desarrollo de métodos analíticos automatizables y de alta sensibilidad para la detección cuantitativa de péptidos de gluten en orina para laboratorios clínicos AT17-5489-USE. **PI: C. Sousa**. 01/02/2020-31/10/2021.

3 Desarrollo de métodos analíticos para la determinación de metabolitos de fármacos para el seguimiento de tratamientos (ATHAME). **PI: C. Sousa**. 10/06/2019- 30/11/2022.

4 Evaluación integral de la adherencia a la dieta y el estado de la mucosa mediante el análisis combinado de péptidos inmunogénicos de gluten (GIP) y calprotectina en muestras de heces de pacientes celíacos (GIPROTEC). **PI: C. Sousa**. 15/02/2018- 31/12/2019.

5 Test doméstico para la monitorización de la dieta sin gluten (GLUTENDETECT). **PI: C. Sousa**. 11/12/2017-24/11/2019.

6 Desarrollo e implementación de metodologías para la detección de alérgenos alimentarios y péptidos inmunogénicos mediente Inmunoensayos, PCR y espectrometría de masas (ALERGOTEST). **PI: C. Sousa**. 25/11/2016-25/11/2019.

Patents:

7 Moreno ML., **Sousa C.,** Rodriguez-Herrera A., Cebolla A. P201400569- PCT/ES2015/070536. Detección de péptidos del gluten en fluidos humanos. Spain. 09/07/2014.

8 **Sousa C.,** Comino I., Real A. Vivas S., Cebolla A. P201001633-PCT/ES2011/000379. Determinación de niveles de péptidos inmunogénicos del gluten en muestras humanas. Spain. 25/07/2012.

9 Comino I., Real a., **Sousa C**. P201001632-PCT/ES2011/000378. Procedimiento para la selección de semillas de cereales aptas para ser consumidas por los enfermos celíacos. Spain. 25/07/2012.

10 Cebolla A., **Sousa C.**, de Lorenzo V. PCT/IB2000/00830. Procedimiento de superexpresión de genes regulada por un circuito genético en cascada. Spain. 22/06/1999.