

## PERSONAL INFORMATION

**Cesar Hernandez Garcia**

## WORK EXPERIENCE

October 2009–Present

**Head of Department of Medicines for Human Use**

Agencia Española de Medicamentos y Productos Sanitarios (Spain)

Responsibility and coordination (over 200 people) in the areas of clinical trials, regulatory affairs, clinical evaluation, quality, pharmacovigilance, coordination with the European Medicines Agency, drug approval through the centralized procedure, pediatric drugs unit, scientific advisory and drug use in special situations

June 2009–October 2009

**Technical Advisor**

Agencia Española de Medicamentos y Productos Sanitarios (Spain)

Deputy to the Head of Department of Medicines for Human Use

May 2005–June 2009

**Rheumatologist**

Hospital Clínico San Carlos (Spain)

Assistance, research and management in the field of rheumatology.

June 2002–May 2005

**Deputy Medical Director**

Hospital Clínico San Carlos (Spain)

Deputy Medical Director in a large hospital in Madrid (about 1,000 beds and 500,000 people in the reference area) with responsibility in the area of medical, hospital emergency and hospital pharmacy.

June 1994–June 2002

**Rheumatologist**

Hospital Clínico San Carlos (Spain)

Assistance, research and management in the field of rheumatology. Emergency assistance in the area of internal medicine. Member of the Commission for Health Technology Assessment at the Hospital Clínico San Carlos.

January 1992–June 1993

**Fellow of the Health Research Fund of the Ministry of Health**

Hospital Clínico San Carlos (Spain)

Basic research in the field of early markers of lymphocyte activation in autoimmune diseases (rheumatoid arthritis and systemic lupus erythematosus) and aging

May 1988–December 1991

**Resident of rheumatology**

Hospital Clínico San Carlos (Spain)

Training as a specialist in rheumatology within the MIR program in the Department of Rheumatology, Hospital Clinico San Carlos, Madrid

## EDUCATION AND TRAINING

1994–1996

**Doctor degree in Medicine (PhD)**

School of Medicine, Universidad Complutense de Madrid (Spain)

Doctoral thesis: "Characterization, regulation and function of the expression of CD69 in rheumatoid arthritis". Cum laude. Annual extraordinary award.

May 1988–December 1991

**Specialist in rheumatology**

Hospital Clínico San Carlos, Madrid (Spain)

1981–1987

**Degree in Medicine and Surgery**

Universidad Complutense de Madrid (Spain)

**ADDITIONAL INFORMATION**
**Expertise**

- (1) Rheumatology; inflammatory diseases, autoimmune diseases; rheumatoid arthritis, uveitis.
- (2) Health Care Management, implementation of new technologies
- (3) Regulatory issues

**Publications**

- Hernández-García C. Biosimilar drugs, myths and reality. *Reumatol Clin.* 2014;10(6):351-352
- Maese J, García De Yébenes MJ, Carmona L, Hernandez-Garcia C; el Grupo de Estudio emAR II. Management of rheumatoid arthritis in Spain (emAR II). Clinical characteristics of the patients. *Reumatol Clin.* 2012 Sep-Oct;8(5):236-42
- Jovani V, Loza E, García de Yébenes MJ, Descalzo MÁ, Barrio JM, Carmona L, Hernandez-Garcia C; en representación del Grupo de estudio emAR. Variability in resource consumption in patients with spondyloarthritis in Spain. Preliminary descriptive data from the emAR II study. *Reumatol Clin.* 2012 May-Jun;8(3):114-9.
- Casals-Sánchez JL, García De Yébenes Prous MJ, Descalzo Gallego MÁ, Barrio Olmos JM, Carmona Ortells L, Hernandez-Garcia C; Grupo de Estudio emAR II. Characteristics of patients with spondyloarthritis followed in rheumatology units in Spain. emAR II study. *Reumatol Clin.* 2012 May-Jun;8(3):107-13.
- Hernandez-Garcia C. [Justification to health managers: cost-benefit of osteoporosis management]. *Reumatol Clin.* 2011 Sep;7 Suppl 2:S13-7.
- Lopez-Gonzalez R, Loza E, Jover JA, Benitez Del Castillo JM, Mendez R, Hernandez-Garcia C, Pato E. Treatment of refractory posterior uveitis with infliximab: a 7-year follow-up study. *Scand J Rheumatol.* 2009 Jan-Feb;38(1):58-62.
- Lopez-Gonzalez R, Hernandez-Garcia C, Abasolo L, Morado I, Lajas C, Vadillo C, Pato E, Fernandez-Gutierrez B, Jover JA, Loza E; emAR Study Group. Differences between rheumatology attending physicians and training residents in the management of rheumatoid arthritis in Spain. *Scand J Rheumatol.* 2008 Nov-Dec;37(6):419-26.
- Abásolo L, Carmona L, Lajas C, Candelas G, Blanco M, Loza E, Hernandez-Garcia C, Jover JA. Prognostic factors in short-term disability due to musculoskeletal disorders. *Arthritis Rheum.* 2008 Apr 15;59(4):489-96.
- Loza E, Jover JA, Rodriguez L, Carmona L; EPISER Study Group. Multimorbidity: prevalence, effect on quality of life and daily functioning, and variation of this effect when one condition is a rheumatic disease. *Semin Arthritis Rheum.* 2009 Feb;38(4):312-9
- Clemente D, Hernandez-Garcia C, Abásolo L, Villaverde V, Lajas C, Loza E, López-González R, Vadillo C, Fernández-Gutiérrez B, Morado I, Angel Jover J; el Grupo de Estudio emAR. [Reduction in time until first treatment with disease modifying treatment in patients with rheumatoid arthritis]. *Reumatol Clin.* 2007 Nov;3(6):245-50.
- Mahr AD, Jover JA, Spiera RF, Hernandez-Garcia C, Fernández-Gutiérrez B, Lavalley MP, Merkel PA. Adjunctive methotrexate for treatment of giant cell arteritis: an individual patient data meta-analysis. *Arthritis Rheum.* 2007 Aug;56(8):2789-97.
- Loza E, Abásolo L, Clemente D, López-González R, Rodríguez L, Vadillo C, Fernández-Gutiérrez B, Macarrón P, Jover JA, Hernandez-Garcia C. Variability in the use of orthopedic surgery in patients with rheumatoid arthritis in Spain. *J Rheumatol.* 2007 Jul;34(7):1485-90.
- Abásolo L, Carmona L, Hernandez-Garcia C, Lajas C, Loza E, Blanco M, Candelas G, Fernández-Gutiérrez B, Jover JA. Musculoskeletal work disability for clinicians: time course and effectiveness of a specialized intervention program by diagnosis. *Arthritis Rheum.* 2007 Mar 15;57(2):335-42.
- Rollín R, Alvarez-Lafuente R, Marco F, Jover JA, Hernandez-Garcia C, Rodríguez-Navas C, López-Durán L, Fernández-Gutiérrez B. Human parvovirus B19, varicella zoster virus, and human herpesvirus-6 in mesenchymal stem cells of patients with osteoarthritis: analysis with quantitative real-

- time polymerase chain reaction. *Osteoarthritis Cartilage*. 2007 Apr;15(4):475-8.
- Abásolo L, Blanco M, Bachiller J, Candelas G, Collado P, Lajas C, Revenga M, Ricci P, Lázaro P, Aguilar MD, Vargas E, Fernández-Gutiérrez B, Hernandez-Garcia C, Carmona L, Jover JA. A health system program to reduce work disability related to musculoskeletal disorders. *Ann Intern Med*. 2005 Sep 20;143(6):404-14.
- Salido M, Macarrón P, Hernandez-Garcia C, D'Cruz DP, Khamashta MA, Hughes GR. Water intoxication induced by low-dose cyclophosphamide in two patients with systemic lupus erythematosus. *Lupus*. 2003;12(8):636-9.
- Carmona L, Hernandez-Garcia C, Vadillo C, Pato E, Balsa A, González-Alvaro I, Belmonte MA, Tena X, Sanmartí R; EMECAR Study Group. Increased risk of tuberculosis in patients with rheumatoid arthritis. *J Rheumatol*. 2003 Jul;30(7):1436-9.
- Vadillo Font C, Hernandez-Garcia C, Pato E, Morado IC, Salido M, Júdez E, Macarrón P, Fernández-Gutiérrez B, Abásolo L, Jover JA. [Incidence and characteristics of tuberculosis in patients with autoimmune rheumatic diseases]. *Rev Clin Esp*. 2003 Apr;203(4):178-82.
- Jover JA, Hernandez-Garcia C, Morado IC, Vargas E, Bañares A, Fernandez-Gutierrez B. Disparate results in studies of methotrexate plus corticosteroids in the treatment of giant cell arteritis: comment on the article by Hoffman et al. *Arthritis Rheum*. 2003 Apr;48(4):1158-9.
- Villaverde, V. Hernandez-Garcia C. González-Álvaro, I. Vargas, E. Abásolo, L. Morado, IC. Lajas, C. Evaluación clínica de los pacientes con artritis reumatoide en España *Revista Española de Reumatología*, 03 2003 ; 30: 110-118
- Hernandez-Garcia C. ¿Hay vida después de los tratamientos biológicos? El papel de otros fármacos modificadores de la enfermedad en la era de los biológicos *Revista Española de Reumatología*, 06 2002 ; 29: 311-315
- González-Álvaro, Hernandez-Garcia C. Variabilidad en el tratamiento de la artritis reumatoide. *Estudio emAR Revista Española de Reumatología*, 03 2002 ; 29: 90-93
- Hernandez-Garcia C. Lázaro y de Mercado, P. GUIPCAR: una guía de práctica clínica para el manejo de la artritis reumatoide en España *Revista Española de Reumatología*, 03 2002 ; 29: 94-98
- Lajas C, Abasolo L, Bellajdel B, Hernandez-Garcia C, Carmona L, Vargas E, Lázaro P, Jover JA. Costs and predictors of costs in rheumatoid arthritis: a prevalence-based study. *Arthritis Rheum*. 2003 Feb 15;49(1):64-70.
- González-Alvaro I, Hernandez-Garcia C, Villaverde García V, Vargas E, Ortiz AM. [Variations in the drug treatment of rheumatoid arthritis in Spain]. *Med Clin (Barc)*. 2002 Jun 1;118(20):771-6.
- Carmona L, Villaverde V, Hernandez-Garcia C, Ballina J, Gabriel R, Laffon A; EPISER Study Group. The prevalence of rheumatoid arthritis in the general population of Spain. *Rheumatology (Oxford)*. 2002 Jan;41(1):88-95.
- Hernandez-Garcia C, González-Álvaro I, Villaverde V, Vargas E, Morado IC, Pato E, Lajas C, Jover JA, y el Grupo de Estudio emAR. Estudio sobre el Manejo de la Artritis Reumatoide en España (emAR). II. Características de los Pacientes. *Rev Esp Reumatol* 2002 ; 29: 130-141
- Villaverde V, Hernandez-Garcia C, González-Alvaro I, Vargas E, Abásolo L, Morado IC, Lajas C, y el Grupo de Estudio emAR. Evaluación clínica de los pacientes con artritis reumatoide en España. *Rev Esp Reumatol* 2002; 28: 413-419
- Hernandez-Garcia C, González-Álvaro I, Villaverde V, Vargas E, Morado IC, Bañares A, Macarrón P, Fernández-Gutiérrez, y el Grupo de Estudio emAR. Estudio sobre el Manejo de la Artritis Reumatoide en España (emAR). I. Características de los centros participantes. *Rev Esp Reumatol* 2001;28:413-419.
- De Miguel S, Galocha B, Jover JA, Bañares A, Hernandez-Garcia C, García-Asenjo JA, Fernández-Gutiérrez B. Mechanisms of CD23 hyperexpression on B cells from patients with rheumatoid arthritis. *J Rheumatol*. 2001 Jun;28(6):1222-8.
- Jover JA, Hernandez-Garcia C, Morado IC, Vargas E, Bañares A, Fernández-Gutiérrez B. Combined treatment of giant-cell arteritis with methotrexate and prednisone. a randomized, double-blind, placebo-controlled trial. *Ann Intern Med*. 2001 Jan 16;134(2):106-14.
- Hernandez-Garcia C, Vargas E, Abásolo L, Lajas C, Bellajdel B, Morado IC, Macarrón P, Pato E, Fernández-Gutiérrez B, Bañares A, Jover JA. Lag time between onset of symptoms and access to rheumatology care and DMARD therapy in a cohort of patients with rheumatoid arthritis. *J Rheumatol*. 2000 Oct;27(10):2323-8.
- Pato E, Bañares A, Jover JA, Fernández-Gutiérrez B, Godoy F, Morado C, Méndez R, Hernandez-Garcia C. Undiagnosed spondyloarthropathy in patients presenting with anterior uveitis. *J Rheumatol*. 2000 Sep;27(9):2198-202.

- Macarrón P, Pato E, Fernández C, Bañares A, Hernandez-Garcia C, Lajas C, Abásolo L, Jover JA. Estudio descriptivo de la cirugía ortopédica realizada a los pacientes atendidos en un servicio de reumatología de un hospital terciario en un período de 5 años. *Rev Esp Reumatol* 2000;27:388-392
- Fernández-Gutiérrez B, Jover JA, De Miguel S, Hernandez-Garcia C, Vidán MT, Ribera JM, Bañares A, Serra JA. Early lymphocyte activation in elderly humans: impaired T and T-dependent B cell responses. *Exp Gerontol*. 1999 Apr;34(2):217-29.
- Vidán MT, Fernández-Gutiérrez B, Hernandez-Garcia C, Serra JA, Ribera JM, Pérez-Blas M, Regueiro JR, Bañares A, Jover JA. Functional integrity of the CD28 co-stimulatory pathway in T lymphocytes from elderly subjects. *Age Ageing*. 1999 Mar;28(2):221-7.
- Bañares A, Hernandez-Garcia C, Fernández-Gutiérrez B, Jover JA. Eye involvement in the spondyloarthropathies. *Rheum Dis Clin North Am*. 1998 Nov;24(4):771-84, ix. Review.
- Hernandez-Garcia C, JA Jover. Uso combinado de fármacos de acción lenta en la Artritis Reumatoide. *Rev Esp Reum* 1998; 26:35-37.
- Fernández-Gutiérrez B, de Miguel S, Morado C, Hernandez-Garcia C, Bañares A, Jover JA. Defective early T and T-dependent B cell activation in systemic lupus erythematosus. *Lupus*. 1998;7(5):314-22.
- Bañares A, Jover JA, Fernández-Gutiérrez B, Benítez del Castillo JM, García J, Vargas E, Hernandez-Garcia C. Patterns of uveitis as a guide in making rheumatologic and immunologic diagnoses. *Arthritis Rheum*. 1997 Feb;40(2):358-70.
- P Collado, JA Jover, A Bañares, B Fernández-Gutiérrez, IC Morado, G Candelas, M Blanco, Hernandez-Garcia C. Características generales y de derivación de una cohorte de pacientes con Artritis Reumatoide. *Rev Esp Reum*.1997; 24: 111-116.
- Hernandez-Garcia C, A Bañares, JA Jover . Aproximación diagnóstica al paciente con inflamación ocular. *Rev Esp Reum* 1997; 24: 168-178.
- Hernandez-Garcia C, P Collado, B Fernández-Gutiérrez . Manifestaciones oculares de la artritis reumatoide. Queratoconjuntivitis seca. *Rev Esp Reum* 1997; 24: 190-195.
- P Collado, Hernandez-Garcia C, JA Jover. Manifestaciones oculares de la artritis crónica juvenil. *Rev Esp Reum*.1997; 24: 203-206
- Serra JA, Fernández-Gutiérrez B, Hernandez-Garcia C, Vidan M, Bañares A, Ribera JM, Jover JA. Early T-cell activation in elderly humans. *Age Ageing*. 1996 Nov;25(6):470-8.
- Hernandez-Garcia C, Fernández-Gutiérrez B, Morado IC, Bañares AA, Jover JA. The CD69 activation pathway in rheumatoid arthritis synovial fluid T cells. *Arthritis Rheum*. 1996 Aug;39(8):1277-86.
- Collado P, Bañares A, Hernandez-Garcia C, Fernández-Gutiérrez B, Ramos P, Morado IC, Godoy FJ, Jover JA. Asistencia reumatológica en una consulta externa de un hospital terciario: experiencia de tres años. *Rev Esp Reumatol* 1996: 23: 9-16.
- Collado P, Bañares A, Hernandez-Garcia C, Fernández-Gutiérrez B, Ramos P, Morado IC, Godoy FJ, Candelas G, Jover JA. Asistencia reumatológica intrahospitalaria en un hospital terciario: experiencia de tres años. *Rev Esp Reumatol* 1996; 23: 78-86.
- Fernández-Gutiérrez B, Hernandez-Garcia C, Bañares AA, Jover JA. CD23 hyperexpression in rheumatoid arthritis: evidence for a B cell hyperresponsiveness to cognate and noncognate T-cell signals. *Clin Immunol Immunopathol*. 1994 Sep;72(3):321-7.
- Bañares AA, Jover JA, Fernández-Gutiérrez B, Benítez del Castillo JM, García J, González F, López JA, Hernandez-Garcia C. Bowel inflammation in anterior uveitis and spondyloarthropathy. *J Rheumatol*. 1995 Jun;22(6):1112-7.
- Benítez del Castillo JM, Toledano N, Bañares A, Hernandez-Garcia C, Arjona M, Diaz Valle D, García Sánchez J Blood-aqueous barrier permeability determination in HLA-B27-positive acute anterior uveitis patients. *International Ophthalmology* 1995; 18: 233-236.
- Hernandez-Garcia C, Benítez del Castillo JM, Morado Quiñoá IC, García Gil de Bernabé J, Godoy Ochoa FJ, Fernández-Gutiérrez B, Jover JA, Bañares AA. Uveitis y enfermedades sistémicas. *Rev Esp Reumatol* 1995; 22: 83-88.
- Fernández-Gutiérrez B, Hernandez-Garcia C, Bañares AA, Jover JA. Characterization and regulation of CD69 expression on rheumatoid arthritis synovial fluid T cells. *J Rheumatol*. 1995 Mar;22(3):413-20.
- Hernandez-Garcia C, Soriano C, Morado C, Ramos P, Fernández-Gutiérrez B, Herrero M, Bañares A, Jover JA. Methotrexate treatment in the management of giant cell arteritis. *Scand J Rheumatol*. 1994;23(6):295-8.

Zhenhong Qu, Hernandez-Garcia C, O'Rourke LO, Planck SR, Manoj K, Rosenbaum JT. Local proliferation of fibroblast-like synoviocytes contributes to synovial hyperplasia. *Arthritis Rheum* 1994; 37: 212-220.

Collado-Ramos P, Bañares AA, Morado-Quiñó IC, Benítez-del-Castillo JM, Hernandez-Garcia C. Longterm remission of corneal melting associated with rheumatoid arthritis after a short course of treatment with oral cyclophosphamide. *J Rheumatol* 1994; 21: 1778-1779.

Ladero JM, Andrés MP, Bañares A, Fernández-Gutiérrez B, Hernandez-Garcia C, Benítez J. Acetylator polymorphism in rheumatoid arthritis. *Eur J Clin Pharmacol* 1993, 45: 279-281.

#### Projects RESEARCH PROJECTS AS PRINCIPAL INVESTIGATOR

Utility of combined treatment with sodium aurothiomalate IM plus methotrexate VO in rheumatoid arthritis. CENTRE: Department of Rheumatology, Hospital Clinico San Carlos, Madrid. DATES: 2003-2005. Project funded by the Health Research Fund of the Spanish Ministry of Health

Study on the Management of Rheumatoid Arthritis in Spain CENTER: Department of Rheumatology, Hospital Clinico San Carlos, Madrid. DATES: 1999-2001. Project funded by the Spanish Society of Rheumatology and Novartis

Long-Term Longitudinal Study in a Cohort of Patients with Rheumatoid Arthritis. CENTRE: Department of Rheumatology. Hospital Clinico San Carlos. Madrid. DATES: 1997-1999. Project funded by the Health Research Fund of the Spanish Ministry of Health

#### RESEARCH PROJECTS AS COLLABORATOR

Development of a Clinical Practice Guideline for the management of rheumatoid arthritis in Spain (member of the panel of experts). CENTER: Advanced Techniques in Health Services Research (Taiss), Madrid. DATES: 1999-2001. Project funded by the Spanish Society of Rheumatology and Novartis

Morphology of uveitis as a guide for etiologic diagnosis (contributor). CENTRE: Department of Rheumatology. Hospital Clinico San Carlos. Madrid. DATES: 1997-1999. Project funded by the Health Research Fund of the Spanish Ministry of Health

Study of CD69 + T cells present in the membrane and synovial fluid from rheumatoid arthritis CENTER: Department of Rheumatology. Hospital Clinico San Carlos. Madrid. DATES: 1990-1994. Project funded by the Health Research Fund of the Spanish Ministry of Health.

Immunohistochemical study of the expression of growth factors in the synovial membrane of rheumatoid arthritis CENTER: Division of Arthritis and Rheumatism. Oregon Health Sciences University. Portland, Oregon, USA. DATES: 1991.

#### INTERNATIONAL COOPERATION PROJECTS

Deputy Project Leader in the European cooperation program (Twinning Light financed by the European Union) of drug regulation in Croatia. Zagreb. DATES: DEC/2010 - JUN/2011

Deputy Project Leader in the European cooperation program (Twinning European Union funded) of drug regulation in Bosnia Herzegovina. Sarajevo-Banja Luka. DATES: Oct/2011 - MAR/2013

#### Memberships Member of the Spanish Society of Rheumatology

1991. Coordinator of a multidisciplinary unit of uveitis in the Hospital Clinico San Carlos (Madrid)

1994 to 2000. Coordinator in the development of multidisciplinary health care protocols at the Hospital Clinico San Carlos (Madrid)

1998 to 2002. Responsible for the database of the ITME-98 program

1998-2000. Member of the Commission of Health Technology and implementation of diagnostic and therapeutic media in the Hospital Clinico San Carlos (Madrid)

1999 to 2001. Member of the expert panel of the first clinical practice guideline for the management of rheumatoid arthritis in Spain (GUIPCAR)

2005. Member of the expert panel of the second edition of the clinical practice guideline for the management of rheumatoid arthritis in Spain (GUIPCAR 2)

Since 2005, a member of the expert group of the Spanish Agency of Medicines and Medical Devices

#### Other Relevant Information

