



## Curriculum Vitae

Personal information **Marcos Timón**

### Work experience

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1. Employer: Agencia Española de Medicamentos y Productos Sanitarios
  - Start date: 082022
  - End date:
  - Position: Head of Unit
  - Activities: Quality Assessment and Supervision of Advanced Therapy Medicinal Products, Biotechnology and other Biological Medicinal products
  - Country: Spain
2. Employer: Agencia Española de Medicamentos y Productos Sanitarios
  - Start date: 012009
  - End date: 072022
  - Position: Head of Service
  - Activities: Quality Assessor of Advanced Therapy, Biotechnology and other Biological Medicinal Products
  - Country: Spain
3. Employer: Agencia Española de Medicamentos y Productos Sanitarios
  - Start date: 082005
  - End date: 012009
  - Position: Quality Assessor
  - Activities: Quality Assessor of Advanced Therapy, Biotechnology and other Biological Medicinal Products
  - Country: Spain
4. Employer: Mologen Molecular Medicines S.L.
  - Start date: 082000
  - End date: 072005
  - Position: Scientific Director
  - Activities: Direction and Supervision of R&D activities in the fields of genetic vaccines and gene therapy
  - Country: Spain
5. Employer: The Edward Jenner Institute for Vaccine Research
  - Start date: 101996
  - End date: 082000
  - Position: Research Scientist
  - Activities: Basic Research in Immunology and Vaccines
  - Country: United Kingdom
6. Employer: Department of Oncology, University College
  - Start date: 101995
  - End date: 091996
  - Position: Research Fellow
  - Activities: Basic Research in Immunology
  - Country: United Kingdom
7. Employer: Tumour Immunology Unit, Imperial Cancer Research Fund
  - Start date: 021993
  - End date: 091995
  - Position: Post\_doctoral Scientist
  - Activities: Basic Research in Immunology
  - Country: United Kingdom
8. Employer: Department of Immunology, Hospital 12 de Octubre
  - Start date: 011988
  - End date: 011993
  - Position: PhD Student
  - Activities: Basic Research in Immunology
  - Country: Spain

### Education and training

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1. Subject: Universidad Complutense de Madrid
  - Start date: 091982
  - End date: 061987
  - Qualification: BSc in Biology (Biochemistry and Genetics)
  - Organisation:
  - Country: Spain
2. Subject: Universidad Complutense de Madrid
  - Start date:
  - End date: 051993
  - Qualification: PhD
  - Organisation: Immunology, Molecular Biology, Cell Biology, Immunodeficiencies
  - Country: Spain

### Additional information

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## Publications

- Rodríguez L, de Felipe P, Martín R, Martínez J, Ordóñez D, Rojo S, Martínez JF, Rincón E, Cejalvo T, Izquierdo I, Montanuy I, Timón M. The Coming of Age of Gene Therapy for the Treatment of Human Diseases: A Regulatory Perspective. *Hum Gene Ther.* 2025 Sep;36(17-18):1103-1117.
- Timón M, Ruiz S. Hospital Exemption for Advanced Therapy Medicinal Products in Spain. *Hum Gene Ther.* 2025 Sep;36(17-18):1095-1098.
- Celis P, Farinelli G, Hidalgo-Simon A, Meij P, Tihaya M, Schüssler-Lenz M, Timón M. EMA commentary on the guideline on quality, nonclinical and clinical aspects of medicinal products containing genetically modified cells. *Br J Clin Pharmacol.* 2024 May;90(5):1203-1212.
- Schuessler-Lenz M, Herberts C, Reischl I, Ruiz S, Celis P, Beuneu C, Kjekens R, Timón M. Marketing Regulatory Oversight of Advanced Therapy Medicinal Products in Europe. *Adv Exp Med Biol.* 2023;1430:1-21.
- Estévez Álamo J, Timón M, Sánchez Afán de Rivera I, Iriarte Torres B, Serrano Castro MA. Clinical Trials on Advanced Therapy Investigational Medicinal Products in Spain (2004-2022): Experience and Challenges for the Future. *Adv Exp Med Biol.* 2023;1430:23-39.
- Loizides U, Dominici M, Manderson T, Rizzi M, Robertson JS, de Sousa Guimaraes Koch S, Timón M, Balocco R. The harmonization of World Health Organization International Nonproprietary Names definitions for cell and cell\_based gene therapy substances: when a name is not enough. *Cytotherapy* 2021; 5:357-366.
- Estévez Álamo J, Timón M, González Gómez Platero C, Doadrio Abad C, Velasco González M, Mingo Ballesteros MY, Martín de la Sierra San Agustín MA, Serrano Castro MA. Clinical trials of advanced therapy investigational medicinal products in Spain: preparing for the European clinical trials regulation. *Cell & Gene Therapy Insights* 2019; 5(11), 1431-1449
- Bonertz A, Roberts G, Slater JE, Bridgewater J, Rabin RL, Hoefnagel M, Timón M, Pini C, Pfaar O, Sheikh A, Ryan D, Akdis C, Goldstein J, Poulsen LK, van Ree R, Rhyner C, Barber D, Palomares O, Pawankar R, Hamerlijnck D, Klimek L, Agache I, Angier E, Casale T, Fernandez\_Rivas M, Haikens S, Jutel M, Lau S, Pajno G, Sturm G, Varga EM, Gerth van Wijk R, Bonini S, Muraro A, Vieths S. Allergen manufacturing and quality aspects for allergen immunotherapy in Europe and the United States: an analysis from the EAACI AIT Guidelines Project. *Allergy* 2018; 73(4):816-826
- Bonertz A, Roberts GC, Hoefnagel M, Timón M, Slater JE, Rabin RL, Bridgewater J, Pini C, Pfaar O, Akdis C, Goldstein J, Poulsen LK, van Ree R, Rhyner C, Barber D, Palomares O, Sheikh A, Pawankar R, Hamerlijnck D, Klimek L, Agache I, Angier E, Casale T, Fernandez\_Rivas M, Haikens S, Jutel M, Lau S, Pajno G, Sturm G, Varga EM, Gerth van Wijk R, Bonini S, Muraro A, Vieths S. Challenges in the implementation of EAACI guidelines on allergen immunotherapy: a global perspective on the regulation of allergen products. *Allergy* 2018; 73(1):64-76.
- Timón M. Proposals for harmonization of allergens regulation in the European Union. *Allergol. Immunopathol.* 2017; 45 (Suppl 1):1-3.
- Salmikangas P, Menezes\_Ferreira M, Reischl I, Tsiftoglou A, Kyselovic J, Borg JJ, Ruiz S, Flory E, Trouvin JH, Celis P, Ancans J, Timón M, Pante G, Sladowski D, Lipnik Stangelj M, Schneider CK. Manufacturing, characterization and control of cell\_based medicinal products: challenging paradigms toward commercial use. *Regen. Med.* 2015; 10(1):65-78.
- Salmerón F, Portela A, Soler M, López S, Somoza MC, Pérez I, Rubio MI, Pérez A, Sagredo A, Ruiz S, Timón M, Frutos G. 50 aniversario del inicio de las campañas de vacunación frente a la poliomielitis en España. Vacunas antipoliomielíticas, erradicación y posterradicación. *Rev Esp Salud Pública* 2013; 87:1-9.
- Salmerón F, Portela A, Ruiz S, Timón M, López S, Hernández R, Pérez I, Sagredo A. La importancia de la regulación y el control de vacunas en la erradicación de enfermedades virales. In *Erradicación y control de las enfermedades producidas por virus*. Editorial Centro de Estudios Ramón Areces, S.A. Madrid, 2012.
- Committee for Advanced Therapies and CAT Scientific Secretariat. Use of unregulated stem\_cell based medicinal products. 2010; *Lancet* 376(9740):514.
- The Committee for Advanced Therapies (CAT), Schneider CK, Salmikangas P, Jilma B, Flamion B, Todorova LR, Paphitou A, Haunerova I, Maimets T, Trouvin JH, Flory E, Tsiftoglou A, Sarkadi B, Gudmundsson K, O'Donovan M, Migliaccio G, Ancans J, Mačulaitis R, Robert JL, Samuel A, Ovelgönne JH, Hystad M, Fal AM, Lima BS, Moraru AS, Turčáni P, Zorec R, Ruiz S, Akerblom L, Narayanan G, Kent A, Bignami F, Dickson JG, Niederwieser D, Figuerola Santos MA, Reischl IG, Beuneu C, Georgiev R, Vassiliou M, Pychova A, Clausen M, Methuen T, Lucas S, Schüssler\_Lenz M, Kokkas V, Buzás Z, Macaleenan N, Galli MC, Liné A, Gulbinovic J, Berchem G, Frączek M, Menezes\_Ferreira M, Vilceanu N, Hrušičko M, Marinko P, Timón M, Cheng W, Crosbie GA, Meade N, di Paola ML, Vandendriessche T, Ljungman P, D'Apote L, Oliver\_Diaz O, Büttel I, Celis P. Challenges with advanced therapy medicinal products and how to meet them. *Nat. Rev. Drug Discov.* 2010; 9(3):195-201.
- Rodríguez\_Cortés A, Ojeda A, Francino O, López-Fuertes L, Timón M, Alberola J. Leishmania infection: laboratory diagnosing in the absence of a "gold standard". *Am. J. Trop. Med. Hyg.* 2010; 82(2):251-256.
- Sánchez-Robert E, Altet L, Alberola J, Rodríguez-Cortés A, Ojeda A, López-Fuertes L, Timón M, Sánchez A, Francino O. Longitudinal analysis of cytokine gene expression and parasite load in PBMC in Leishmania infantum experimentally infected dogs. *Vet. Immunol. Immunopathol.* 2008; 125:168-175.
- Rodríguez-Cortés A, Ojeda A, López-Fuertes L, Timón M, Altet L, Solano-Gallego L, Sánchez-Robert E, Francino O, Alberola J. Vaccination with plasmid DNA encoding Kmp\_11, TSA, LACK and gp63 does not protect dogs against Leishmania infantum experimental challenge. *Vaccine* 2007; 25:7962-7971.
- Rodríguez-Cortés A, Ojeda A, López-Fuertes L, Timón M, Altet L, Solano-Gallego L, Sánchez\_Robert E, Francino O, Alberola J. A long term experimental study of canine visceral leishmaniasis. *Int. J. Parasitol.* 2007; 37:683-693.
- Hoffmann F, Timón M, Wittig B. Gene transfer in corneal transplantation. In *Progress in gene therapy research*. Redberry GW ed. Nova Science Publishers, Inc. New York. 2005.
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- Moreno S, Timón M. DNA vaccination: an immunological perspective. *Inmunología* 2004; 23:41-55.
- López-Fuertes L, Pérez-Jiménez E, Vila-Coro AJ, Sack F, Moreno S, König SA, Junghans C, Wittig B, Timón M, Esteban M. DNA vaccination with linear minimalistic (MIDGE) vectors confers protection against Leishmania major infection in mice. *Vaccine* 2002; 21 (3\_4): 247-257.
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- Díaz del Pozo E, Beverley PCL, Timón M. Genomic structure and sequence of the leukocyte common antigen (CD45) from the pufferfish *Fugu rubripes* and comparison with its mammalian homologue. *Immunogenetics* 2000; 51:838-846.
- Goff LK, van Soest S, Timón M, Tchilian E, Beverley PCL. Protein tyrosine phosphatase receptor type C polypeptide

(PTPRC) on human chromosome band 1q31.q32 localizes with marker D1S413 on a 610\_Kb yeast artificial chromosome. *Cytogenet. Cell Genet.* 1999; 87:223-224.

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-Timón M, Elgar G, Habu S, Okumura K, Beverley PCL. Molecular cloning of major histocompatibility complex class I cDNAs from the pufferfish *Fugu rubripes*. *Immunogenetics* 1998; 47:170-173.

-Timón M, Beverley PCL. Identification of an intragenic promoter in the human CD45 gene. *Biochem. Soc. Trans.* 1997; 25: S177.

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-Martín-Villa JM, Luque I, Martínez-Quiles N, Corell A, Regueiro JR, Timón M, Arnaiz-Villena A. Diploid expression of human leukocyte antigen class I and class II molecules on spermatozoa and their cyclic inverse correlation with inhibin concentration. *Biol. Reprod.* 1996; 55:620-629.

-Arnaiz-Villena A, Rodríguez-Gallego C, Timón M, Corell A, Pacheco A, Alvarez-Zapata D, Madroño A, Iglesias P, Regueiro JR. Diseases involving the T-cell receptor/CD3 complex. *Crit. Rev. Oncol/Hematol.* 1995; 19:131-147.

-Rodríguez-Gallego C, Arnaiz-Villena A, Corell A, Manzanares J, Timón M, Pacheco A, Regueiro JR. Primary T lymphocyte immunodeficiency associated with a selective impairment of CD2, CD3, CD43 (but not CD28)-mediated signal transduction. *Clin. Exp. Immunol.* 1994; 97: 386-391.

-Góngora R, Corell A, Regueiro JR, Carasol M, Rodríguez-Gallego C, Paz-Artal E, Timón M, Allende L, Arnaiz-Villena A. Peripheral blood reduction of memory (CD29+, CD45RO+, and "bright" CD2+ and LFA\_1+) T lymphocytes in Papillon-Lefevre Syndrome. *Human Immunol.* 1994; 41: 185-192.

-Timón M, Arnaiz-Villena A, Ruiz-Contreras J, Ramos-Amador JT, Pacheco A, Regueiro JR. Selective impairment of T lymphocyte activation through the T cell receptor/CD3 complex after Cytomegalovirus infection. *Clin. Exp. Immunol.* 1993; 94:38-42.

-Timón M, Arnaiz-Villena A, Rodríguez-Gallego C, Pérez-Aciego P, Pacheco A, Regueiro JR. Selective disbalances of peripheral blood T lymphocyte subsets in human CD3gamma deficiency. *Eur. J. Immunol.* 1993; 23:1440-1444.

-Timón M, Arnaiz-Villena A, Rodríguez-Gallego C, Iglesias-Casarrubios P, Pacheco A, Regueiro JR. T lymphocyte signalling defects and immunodeficiency due to the lack of CD3gamma. *Immunodeficiency* 1993; 4: 121-129.

-Alarcón B, Terhorst C, Timón M, Arnaiz-Villena A, Pérez-Aciego P, Regueiro JR. Congenital T-cell receptor immunodeficiencies in man. In *Immunodeficiencies*. Rosen FS, Seligmann eds. Harwood Academic, Chur (Switzerland), pp 155-166, 1993.

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-Arnaiz-Villena A, Timón M, Corell A, Pérez-Aciego P, Martín-Villa JM, Regueiro JR. Primary immunodeficiency caused by mutations in the gene encoding the CD3gamma subunit of the T lymphocyte receptor. *N. Engl. J. Med.* 1992; 327:529-533.

-Pérez-Aciego P, Alarcón B, Arnaiz-Villena A, Terhorst C, Timón M, Segurado OG, Regueiro JR. Expression and function of a variant T cell receptor complex lacking CD3gamma. *J. Exp. Med.* 1991; 174:319-326.

-Regueiro JR, Pérez-Aciego P, Timón M, Morales P, Pérez-Blas M, Arnaiz-Villena A. T cell function in patients with impaired antibody responses to polysaccharide antigens. *Reply. Eur. J. Immunol.* 1991; 21: 2293-2296.

-Timón M, Arnaiz-Villena A, Pérez-Aciego P, Morales P, Benmamar D, Regueiro JR. A diallelic RFLP of the CD3-epsilon chain of the clonotypic T-ymphocyte receptor is not associated with certain autoimmune diseases. *Hum. Genet.* 1991; 86:363-364.

## Projects

Patents 1-Timón M, López-Fuertes L. DNA\_expression construct for treatment of infections with leishmaniasis. Validity in: Europe (EP 1432805), USA (US 10/816,591) and China (CN 02819554.X).

2-Timón M, Moreno S. Means for improving immune response. Validity in: Europe (EP 1432439A2), USA (US 10/816,465) and China (CN 02819588.49).

3-Wittig B, López-Fuertes L, Timón M. Mittel zur behandlung von infektionen mit Leishmaniose. Validity in Europe

## Memberships

-Alternate member for Spain at the Committee for Advanced Therapies, European Medicines Agency (EMA)

-Member of the Quality Innovation Group, EMA.

-Member of the Allergens Working Party at the European Directorate for the Quality of Medicines.

-Advisor to the INN expert group of the WHO.

## Other Relevant Information