



## Curriculum Vitae

Personal information **Maria Luisa Casini**

### Work experience

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1. Employer: AIFA \_ Italian Medicine Agency, Rome
  - Start date: 03/2007
  - End date:
  - Position: Senior assessor - Pharmacovigilance
  - Activities:
  - Country: Italy
2. Consultancy: IC Pharma s.r.l., Rome
  - Start date: 01/2005
  - End date: 03/2007
  - Position: Scientific Consultant
  - Activities:
  - Country: Italy
3. Consultancy: AMSA Pharmaceutical Laboratories \_ IBSA Corporation (IBSA Institut Biochimique SA)
  - Start date: 02/1999
  - End date: 03/2007
  - Position: Qualified Person for Pharmacovigilance (Drug Safety Manager)
  - Activities:
  - Country: Italy
4. Consultancy: RSF \_ Ricerca e Sviluppo del Farmaco s.a.s., Rome
  - Start date: 02/1999
  - End date: 03/2007
  - Position: Scientific Consultant
  - Activities:
  - Country: Italy

### Education and training

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1. Subject: Second level Professional Master in Clinical Research
  - Start date: 11/2001
  - End date: 12/2002
  - Qualification: Master in Clinical Research
  - Organisation: University of Rome "Tor Vergata"
  - Country: Italy
2. Subject: Specialisation in Pharmacology
  - Start date: 11/1997
  - End date: 11/2001
  - Qualification: Specialist in Pharmacology
  - Organisation: University of Rome "Sapienza"
  - Country: Italy
3. Subject: Doctorate in Pharmacology, Pharmacognosy and Toxicology
  - Start date: 11/1993
  - End date: 07/1997
  - Qualification: PhD Philosophy Doctor in Pharmacology, Pharmacognosy and Toxicology
  - Organisation: University of Rome "Sapienza"
  - Country: Italy

### Additional information

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#### Publications

#### SCIENTIFIC BOOKS AND MONOGRAPHS

- 1) Jasonni VM, Chiossi G e Casini ML (2000)  
The Polycystic ovary  
In: "La Policistosi Ovarica: una patologia di interesse multidisciplinare" G.C Di Renzo, A. Ferrari, V.M. Jasonni Eds. Verduci editore, pag. 1\_15
- 2) Unfer V, Casini ML, Costabile L (2004)  
Role of polyunsaturated fatty acids in preterm labor  
In: "Nutrizione Perinatale", GC Di Renzo e A Alberti, Gruppo Editoriale EDITEAM s.a.s., pp.27\_30
- 3) Unfer V, Casini ML, Gerli S, Costabile L (2005)  
Cap. 8: Fisiologia del Sistema riproduttivo femminile e maschile  
In: "Ginecologia ed Ostetricia", Vol. 1, 1a Ed., Verduci Editore
- 4) Unfer V e Casini ML (a cura di) (2006)  
Alopecia androgenetica femminile: una patologia di interesse multidisciplinare.  
1a Edizione, FrancoAngeli Editore
- 5) Unfer V, Schimberni M, Sbracia M, Morgia F, Casini ML (2007)  
Chapter 12 \_ Blastocyst Culture and Transfer in Oocyte donation  
In: "Donor Egg IVF", Gautam N Allahbadia Editor, Jaypee Medical Publishers, New Delhi, 1st Edition.

6) Venegoni M, Casini ML, Tartaglia L, Pagano I. (2009)  
Pharmacovigilance and contrast agents.  
In: I mezzi di contrasto in Diagnostica per Immagini – Raccomandazioni all'uso, reazioni avverse e trattamento, Omicron Editrice, Genova

PUBLICATIONS ON SCIENTIFIC JOURNALS (from 1995)

- 1) Saso L, Casini ML, Posta S, Valentini G, Alcaro S, and Silvestrini B (1995) Effect of selected substances on heat induced aggregation of albumin examined by gel permeation HPLC and polyacrylamide gel electrophoresis. *Pharm Res.*, vol 31, Suppl. 1: 214
- 2) Saso L, Casini ML, Mattei E, Valentini G e Mazzanti G (1996) Alpha\_Hydroxy Acids, Anti\_age Compounds, Protect Albumin Against Heat\_induced Denaturation *Phytother Res.*, Vol. 10, S53\_S55
- 3) Tita B, Bolle P, Baldazzi C, Casini ML, Faccendini P, Tucci P (1996) Responsiveness of rabbit detrusor, urethra, and trigone strips to imipramine and trazodone. *Eur Neuropsychopharm.*, Vol. 6, Suppl. 4: 82\_83
- 4) Tita B, Bolle P, Baldazzi C, Casini ML, Faccendini P, Tucci P (1996) Responsiveness of rabbit prostate strips to imipramine and trazodone. *Eur Neuropsychopharm.*, Vol. 6, Suppl. 4: 83
- 5) Bolle P, Casini ML, Mazzanti G, Palmery M, Tita B, Tucci P (1966)  
Facilitating effect of harmaline on phenylephrine contraction in rabbit urethra  
*Phytother Res.*, 10: S42\_S44
- 6) Saso L, Panzironi C, Braghiroli L, Valentini G, Casini ML, Mattei E, de Feo G, Mazzanti G e Silvestrini B (1996)  
Implicazioni farmacologiche della stabilizzazione dell'albumina sierica da parte di sostanze endogene ed esogene  
*Actes du XXIIe Congres International de la Societe de Pharmacie de la Mediterranée Latine – Numero special des Amis du Musee de la Pharmacie:* p.47\_50
- 7) Saso L, Casini ML, Valentini G, Mattei E, Panzironi C and Silvestrini B (1998)  
Development of an HPLC assay to study the effect of endogenous and exogenous substances on heat\_induced aggregation of human serum albumin  
*Clin Chem Lab Med.*, 36(3): 155\_162
- 8) Saso L, Valentini G, Casini ML, Mattei E, Panzironi C, Silvestrini B (1998)  
Development of a turbidimetric assay to study the effect of urinary components on calcium oxalate precipitation  
*Urol Int.* 60: 47\_52
- 9) Saso L, Valentini G, Casini ML, Mattei E, Braghiroli L, Mazzanti G, Panzironi C, Grippa E and Silvestrini B (1998)  
Inhibition of protein denaturation by fatty acids, bile salts and other natural substances: a new hypothesis for the mechanism of action of fish oil in rheumatic diseases  
*Jpn J Pharmacol.*, 79:89\_99
- 10) Baldazzi C, Leone MG, Casini ML and Tita B (1998)  
Effect of the major alkaloid of *Hydrastis canadensis* L., berberine, on rabbit prostate strips  
*Phytother Res.*, 12: 589\_591
- 11) Saso L, Valentini G, Mattei E, Panzironi C, Casini ML, Grippa E and Silvestrini B (1999)  
Stabilization of rat serum proteins following oral administration of fish oil  
*Archives of Pharmacal Research*, 22: 485\_490
- 12) Saso L, Valentini G, Casini ML, Grippa E, Gatto MT, Leone MG and Silvestrini B (2001)  
Inhibition of heat\_induced denaturation of albumin by nonsteroidal antiinflammatory drugs (NSAIDs): pharmacological implications.  
*Archives of Pharmacal Research*, 24: 150\_158
- 13) Tita B, Leone MG, Casini ML, Corubolo C, Bordi F, Guidolin D, Fumagalli E, Romanelli L, Mattioli F, Fehér J, Saso L (2001)  
Corneal toxicity of xylazine and clonidine, in combination with ketamine, in the rat.  
*Ophthalmic Research*, 33: 345\_352
- 14) Mignosa MM, Casini ML, Minozzi M, Baccaille Z, Belia N, Di Renzo GC (2002)  
Studio sull'efficacia e la tollerabilità di una nuova formulazione farmaceutica multivitaminica in gravidanza (Prontogral®)  
*Rivista di Ginecologia Consultoriale*, 14 (2): 71\_75
- 15) Unfer V, Costabile L, Casini ML, Borghi F, Paragona M, Marzano F, Agostini R (2002)  
Trattamento delle vaginosi batteriche in gravidanza con i sali d'ammonio quaternari  
*Rivista di Ginecologia Consultoriale*, 14 (3\_4): 333\_8
- 16) Di Renzo GC, Mignosa MM, Casini ML, Rossetti D, Gerli S, Di Paolo AM. (2002)  
Efficacia clinica dei sali d'ammonio quaternari nel trattamento delle vaginosi batteriche  
*Rivista di Ginecologia Consultoriale*, 14 (3\_4): 329\_32
- 17) Casini M.L., Unfer V, Costabile L, Gerli S, Agostini R, Di Renzo GC (2003)  
Oral vs. intramuscular progesterone supplementation in IVF\_ET cycles: a randomized study  
*Human Reproduction*, 18 (suppl):106
- 18) Agostini R, Casini ML, Costabile L, Paragona M, Marzano F, Unfer V. (2003)  
Il progesterone nella pratica clinica ostetrico\_ginecologica: una revisione critica della letteratura internazionale  
*Giornale Italiano di Ostetricia e Ginecologia*, 25(11\_12):475\_82
- 19) Unfer V, Casini ML, Paragona M, Marzano F, Agostini R. (2004)  
Phytoestrogens supplementation during IVF\_ET cycles: a prospective, controlled, randomized trial.  
*Gynecological Endocrinology*, 18 (suppl. 1):189
- 20) Costabile L, Casini ML, Gerli S, Di Renzo GC, Unfer V (2004)  
Intramuscular progesterone vs 17alpha\_hydroxyprogesterone caproate in in vitro fertilization: a prospective randomized study.  
*Gynecological Endocrinology*, 18 (suppl. 1):232
- 21) Casini ML, Costabile L, Unfer V, Gerli S, Di Renzo GC (2004)  
N\_3 fatty acids improve uterine blood flow in the peri\_implantation period. A prospective clinical study.  
*Gynecological Endocrinology*, 18 (suppl. 1):353
- 22) Unfer V, Casini ML, Costabile L, Gerli S, Mignosa M, Di Renzo GC (2004)

- Inhibition of gonadotropin surge by a brief mid\_cycle regimen of ethinylestradiol and ciproterone acetate: possible role in in vitro fertilization  
Gynecological Endocrinology, 18(suppl. I):355
- 23) Unfer V, Casini ML, Costabile L, Mignosa M, Gerli S, Di Renzo GC (2004)  
Endometrial effects of long term treatment with phytoestrogens: a randomized, double\_blind, placebo controlled study  
Fertility and Sterility, 82(1):145\_148, quiz 265.
- 24) Unfer V, Casini ML, Costabile L, Mignosa M, Gerli S, Di Renzo GC (2004)  
High dose of phytoestrogens can reverse the antiestrogenic effects of clomiphene citrate on endometrium in patients undergoing intrauterine insemination: a randomized trial  
Journal of the Society for Gynecologic Investigation, 11(5): 323\_8  
Related editorial: Casper RF. Phytoestrogens, clomiphene, and the uterus.  
Journal of the Society for Gynecologic Investigation, 11(5): 261\_2
- 25) Unfer V, Casini ML, Costabile L, Gerli S, Baldini D, Di Renzo GC (2004)  
17 alpha\_hydroxyprogesterone caproate vs intravaginal progesterone in IVF\_ET cycles. A prospective randomized study.  
Reproductive Biomedicine Online, 9(1):17\_21
- 26) Gerli S, Casini ML, Unfer V, Costabile L, Bini V, Di Renzo GC (2004)  
Recombinant versus urinary follicle\_stimulating hormone (FSH) in intrauterine insemination (IUI) cycles: a prospective randomized analysis of cost effectiveness.  
Fertility and Sterility, 82(3):573\_8.
- 27) Gerli S, Casini ML, Unfer V, Costabile L, Mignosa M, Di Renzo GC (2004)  
Ovulation induction with urinary FSH or recombinant FSH in PCOS patients: a prospective randomized analysis of cost effectiveness.  
Reprod Biomed Online, 9(5):494\_9.
- 28) Unfer V, Casini ML, Gerli S, Costabile L, Mignosa M, Di Renzo GC (2004)  
Phytoestrogens may improve the pregnancy rate in in vitro fertilization\_embryo transfer cycles: a prospective, controlled, randomized trial.  
Fertility and Sterility, 82(6):1509\_13
- 29) Unfer V, Casini ML, Costabile L, Paragona M, Marzano F, Agostini R (2004)  
Fitoestrogeni: ripercussioni endometriali  
International Up To Date, "Perimenopausa e terza età: quali terapie?", 250: 359\_364
- 30) Unfer V, Casini ML, Marelli G, Costabile L, Gerli S, Di Renzo GC (2005)  
Different routes of progesterone administration and polycystic ovary syndrome: A review of the literature.  
Gynecol Endocrinol. 21(2):119\_27.
- 31) Facchinetti F, Casini ML, Costabile L, Malavasi B, Unfer V (2005)  
Diclofenac pyrrolidine versus Ketoprofen for the relief of pain from episiotomy: a randomized controlled trial.  
Acta Obstet Gynecol Scand. 84(10):951\_5.
- 32) Agostini R, Casini ML, Costabile L, Paragona M, Marzano F, Unfer V.(2005)  
Efficacy and safety of 17alpha\_hydroxyprogesterone caproate in hormone replacement therapy.  
Gynecol Endocrinol 21(5): 265\_267
- 33) Casini ML, Marelli G, Papaleo E, Ferrari A, D'Ambrosio F, Unfer V. (2006)  
Psychological assessment of the effects of treatment with phytoestrogens on postmenopausal women: a randomized, double\_blind, crossover, placebo\_controlled study.  
Fertil Steril. 85(4):972\_8.
- 34) Casini ML, Rossi F, Agostini R, Unfer V. (2006)  
Effects of the position of fibroids on fertility.  
Gynecol Endocrinol. 22(2):106\_9.
- 35) Unfer V, Di Renzo GC e Casini ML (2006)  
The Use of Progesterone in Clinical Practice: Evaluation of its Efficacy in Diverse Indications Using Different Routes of Administration.  
Current Drug Therapy 1(2):211\_219
- 36) Casini ML, Gerli S, Unfer V. (2006)  
An infertile couple suffering from oligospermia by partial sperm maturation arrest: Can phytoestrogens play a therapeutic role? A case report study.  
Gynecol Endocrinol. 22(7):399\_401.
- 37) Casini ML. (2007)  
Ritiro del Lumiracoxib.  
BIF \_ Bollettino d'Informazione sui Farmaci, Anno XIV N. 4:183.
- 38) Casini ML, Cupani C. (2008)  
Fibrosi sistemica nefrogenica e gadolinio  
BIF \_ Bollettino d'Informazione sui Farmaci, Anno XV N. 2:68\_71.
- 39) Casini ML, Cupani C. (2008)  
Appropriatezza prescrittiva della ticlopidina  
BIF \_ Bollettino d'Informazione sui Farmaci, Anno XV N. 4:172\_5.
- 40) Casini ML, Pagano I. (2008)  
Blue Patent V: quali rischi nasconde questo colorante?  
BIF \_ Bollettino d'Informazione sui Farmaci, Anno XV N. 5:219\_222.
- 41) Casini ML. (2009)  
Blue Patent V: colorante e reazioni anafilattiche  
ReA Reazioni – Bollettino di Farmacovigilanza dell'AIFA, anno 3, n. 9, febbraio 2009, p. 6
- 42) Casini ML e Renda F. (2010)  
Tantum rosa ed errori terapeutici  
ReA Reazioni – Bollettino di Farmacovigilanza dell'AIFA, anno 4, n. 16, febbraio 2010, p. 7
- 43) Davanzo F, Settimi L, Sesana F, Milanese G, Maiozzi P, Urbani E, Cossa L, Casini ML, Ferrazin F e Rivolta AL. (2010)  
Assunzione per via orale di lavande vaginali prima e dopo l'avvio di una campagna di promozione televisiva. Le osservazioni effettuate dal CAV di Milano  
Bollettino Epidemiologico Nazionale, Inserto del Notiziario dell'ISS Volume 23 – Numero 12 Dicembre 2010

- 44) Settimi L, Davanzo F, Lauria L, Casini ML, Ferrazin F. (2012)  
Oral ingestion of a topical benzydamine hydrochloride-containing gynaecological preparation in association with television advertising in Italy: analysis of cases managed by a National Poison Control Centre  
British Medical Journal Open 2012; 2: e000204. doi:10.1136/ bmjopen\_2011\_000204
- 45) Trotta F, Tartaglia L, Alessandro A, Casini ML, Capponi S, Ferrazin F. (2012)  
Programme for funding Active Pharmacovigilance Projects in the Italian Regions  
Drug Safety October 1, 2012 \_ Volume 35 \_ Issue 10 \_ ppg 877\_970
- 46) Viola E, Opri S, Moretti U, Leone R, Casini ML, Ruggieri S, Minore C, Conforti A. (2014)  
 $\alpha_1$  Adrenergic receptor antagonists and gynecomastia. A case series from the Italian spontaneous reporting system and VigiBase<sup>TM</sup>.  
Eur J Clin Pharmacol. 70(8):1003\_9. Epub 2014 Jun 3.
- 47) Carnovale C, Brusadelli T, Casini ML, Renda F, Ruggieri S, Pimpinella G, Radice S, Clementi E. (2015)  
Drug-induced anaemia: a decade review of reporting to the Italian Pharmacovigilance data\_base.  
Int J Clin Pharm. 2015 Feb;37(1):23\_6. Epub 2014 Dec 17.
- 48) Davanzo F, Settimi L, Giordano F, Casini ML, Ferrazin F. (2015)  
Inadvertent oral administration of methylethergometrine maleate to children in the first months of life: from surveillance to prevention.  
Pharmacoepidemiol Drug Saf. 2015 Mar;24(3):269\_75. Epub 2015 Feb 2.

## Projects

## Memberships

## Other Relevant Information

- From June 2017 \_ current: Chair of the CMDh Working Party on Pharmacovigilance Procedures Work Sharing
- From December 2019 \_ current: EU Member of the IPRP WG on Pharmacovigilance
- From April 2018 \_ current: Member of the Harmonisation of RMP Project (HaRP) Group
- From November 2011 \_ current: European Commission Topic Leader of the International Council on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use M1 MedDRA Point to Consider Working Group (ICH)
- From May 2010 \_ current: Member of the EudraVigilance Expert Working Group (EMA)
- From June 2012 \_ to December 2020: Core Member of the Incident Review Network (EMA)
- From October 2012 to October 2018: Italian Alternate Member at the CMDh \_ Coordination Group for Mutual Recognition and Decentralised Procedures – Human (HMA)
- From February 2009 \_ to June 2017 Member of the Pharmacovigilance Procedures Work Sharing Working Party (formerly PSUR Work Sharing Working Party) (EMA)
- From January 2009 \_ July 2012: Italian a. Delegate at the CHMP Pharmacovigilance Working Party (EMA)