

PERSONAL INFORMATION

Maria Francesca Cometa

WORK EXPERIENCE

- 2001- Present **Researcher- Expert for toxicological aspects of preclinical test**
Istituto Superiore di Sanità (Italian National Public Health Institute) (Italy)
Evaluation of the dossier for preclinical test required to the Phase I trial authorization of drug in relation to the Law by Decree n° 439/2001Phase I IMPD dossier evaluation
- 2001- Present **Researcher- Expert for toxicological aspects of preclinical test**
Istituto Superiore di Sanità (Italy)
Expert to evaluation preclinical experimental models according to the Directives of the Council of the European Communities (86/609/EEC) on animal care
- 2002- 2012 **Junior GLP ispector**
Ministry of Health (Italy)
Expert of the Ministry of Health in relation to the Law by Decree n°50, 2007 that carry into effect the 2004/9/EC and 2004/10/EC Directives regarding inspection and verification of Good Laboratory Practice (GLP)
- 2003- Present **Researcher- Expert for toxicological aspects of preclinical test**
Istituto Superiore di Sanità (Italy)
Expert for the toxicological aspects of National Commission on Cell Therapy at Istituto Superiore di Sanità to participate at the drafting of the Guidelines on phase I clinical trial in accordance with Law Decree 439/2001
- 2004- Present **Researcher- Expert for toxicological aspects of preclinical test**
Istituto Superiore di Sanità (Italy)
Preclinical Assessor for Centralised, Decentralised and Mutual recognition proceduresPreclinical Assessor for National Authorization of herbal medicinal product
- 2004- Present **Researcher- Expert for toxicological aspects of preclinical test**
Faculty of Pharmacy, University La Sapienza, Rome (Italy)
Teaching contract for University in:-General Toxicology -Pharmacological and toxicological methods in herbal science University teaching and experimental degree thesis advisor
- October 2006-October 2006 **Teaching on the issues for the nonclinical assessment for Competent Authority (Phase I clinical trial) and EMA**
AIFA (Italian Medicines Agency) (Italy)
Annual Preclinical Assessor Meeting
- 2008- Present **Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization**
Istituto Superiore di Sanità (Italy)
Rapporteur for applicants of new Clinical Trial Application and responsible of the transmission outside the Istituto Superiore di Sanità (mainly to the OSSC- National Monitoring Centre on Clinical Research with Medicine) at the AIFA
- 2008- Present **Member of Scientific Secretariat of Italian Competent Authority for Phase I**

Clinical Trial Authorization

Istituto Superiore di Sanità (Italy)

Teaching in courses for University Masters in Clinical Trials

- December 2008-December 2008 **Teaching on the issues for the nonclinical assessment of dossiers for Competent Authority (Phase I clinical trial) and EMA**
Istituto Nazionale Per lo studio e la cura dei tumori (Italy)
Updating course in biological therapy for tumors: Scientific and Regulating aspect
- 2009- Present **Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization**
Istituto Superiore di Sanità (Italy)
Teaching in national and international meeting on Phase I Clinical Trial
- 2009- 2011 **Teaching on the issues for the nonclinical assessment of dossiers for Competent Authority (Phase I clinical trial) and EMA**
Istituto Internazionale di Ricerca (Italy)
Meeting on Phase I Clinical Trial
- 2010- Present **Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization**
Istituto Superiore di Sanità (Italy)
Teaching in courses for Assessors involved in the evaluation of dossier (Investigational Medicinal Product Dossier, Investigators Brochure and Clinical Protocol) of phase I Clinical Trial Application
- 2012-February 2016 **Senior/Coordinator GLP Inspector**
Ministry of Health (Italy)
Performing GLP inspections (reports)
- November 2013-November 2013 **Teaching on the issues for the nonclinical assessment of dossiers for Competent Authority (Phase I clinical trial) and EMA**
Istituto Superiore di Sanità (Italy)
Course on translational application for investigational ATMPs (Advanced Therapy Medicinal Products)
- November 2015- Present **Teaching**
Istituto Superiore di Sanità (Italy)
Course on Technical Scientific evaluation of experimental projects with animals according to 2010/63/EU Directive which updates and replaces the 1986 Directive 86/609/EEC on the protection of animals used for scientific purposes.
- February 2018- Present **Secretary of Phase I clinical trial Committee**
Ministry of Health (Italy)
Scientific technical activity for the committee
- October 2018- Present **Italian delegate**
EMA/AIFA (Italy)
EMA GLP Inspectors Working Group

EDUCATION AND TRAINING

- 1989- 1991 **Guest worker for phytochemical studies on medicinal plants**
Laboratory of Phytochemicals, Faculty of Pharmacy, University La Sapienza (Italy)
phytochemistry and pharmacognosy
- July 1991- **Degree in pharmacy (summa cum laude)**
Laboratory of Phytochemicals, Faculty of Pharmacy, University La Sapienza (Italy)
phytochemistry and pharmacognosy
- 1993- 1997 **PhD in Pharmacology, Pharmacognosy and Toxicology**
Department of Pharmacology of Natural Substances and General Physiology, Faculty of Pharmacy, University La Sapienza (Italy)
- March 1994-April 1994 **Guest worker for phytochemical studies on medicinal plants**
Faculty of Pharmacy, Universidad Catolica del Peru - Lima - Peru (Peru)
phytochemistry and pharmacognosy
- March 1995-April 1995 **Guest worker for phytochemical studies on medicinal plants**
Faculty of Biology, Botanical Institute and Garden, Studentski trg 6, 11000 Belgrade (Serbia)
phytochemistry and pharmacognosy
- 1997- 2000 **Postgraduate Research Fellowship**
Department of Pharmacology of Natural Substances and General Physiology, Faculty of Pharmacy, University La Sapienza (Italy)
- 2000- 2001 **Research grant in Pharmacognostic Science**
Department of Pharmacology of Natural Substances and General Physiology, Faculty of Pharmacy, University La Sapienza (Italy)
- 2001- Present **Confirmed Researcher**
Section of Biochemical Pharmacology and Technical Scientific Advice Coordination Unit, Department of Therapeutic Research and Medicines Evaluation- Istituto Superiore di Sanità (Italy)
- 2002- 2016 **Toxicology expert**
Ministry of Health (Italy)
- 2003- 2003 **Update on the issues for authorization of animal use in preclinical test**
Istituto Superiore di Sanità (Italy)
- October 2004-October 2004 **Update on the issues for the nonclinical assessment of dossiers for EMEA**
BfArM (Federal Institute for Drugs and Medical Devices) (Germany)
- November 2005-November 2005 **Update on the issues for the nonclinical assessment of dossiers for EMEA**
HESI (ILSI Health and Environmental Science Institute) ()

ADDITIONAL INFORMATION

Expertise

Evaluation Activity: Non clinical Assessor

Scientific Technical Secretariat of the Committee for the Evaluation of Phase I clinical trial dossiers conducted in Italy

Teaching in Master on regulatory sciences for Phase I clinical trial applications.

Teaching in Courses on the applications submitted according to DIRECTIVE 2010/63/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2010 on the protection of animals used for scientific purposes

Publications

Main Scientific publication (2003-2017):

L. Ricceri, N. Markina, A. Valanzano, S. Fortuna, M.F. Cometa, A. Meneguz and G. Calamandrei. Developmental exposure to chlorpyrifos alters reactivity to environmental and social cues in adolescent mice. *Toxicology and Applied Pharmacology* 191: 189-201 (2003).

G. Migliaccio, U Testa, MF Cometa, S Fais, P Chistolini, M. Bignami, U. Agrimi, E. Proietti, E.M. Coccia. Linee guida sui prodotti per terapia cellulare. *Notiziario dell'Istituto Superiore di Sanità*;17(7-8):9-14 (2004).

M.F.Cometa, P. Lorenzini, S. Fortuna, M.T. Volpe, A. Meneguz, M. Palmery. In vitro inhibition effect of aflatoxin B1 on mouse brain acetylcholinesterase activity. *Toxicology* 206: 125-135 (2005).

L. Ricceri, A. Venerosi, F. Capone, M. F. Cometa, P. Lorenzini, S. Fortuna and G. Calamandrei. Developmental neurotoxicity of organophosphorous pesticides: fetal and neonatal exposure to chlorpyrifos alters sex-specific behaviors at adulthood in mice. *Toxicological Sciences* 93(1): 105-13 (2006).

M. F. Cometa, F. M. Buratti, S. Fortuna, P. Lorenzini, M. T. Volpe, E. Testai and A. Meneguz. Cholinesterase inhibition and alterations of hepatic metabolism by acute and repeated chlorpyrifos administration in mouse model. *Toxicology* 234: 90-102 (2007).

M.F.Cometa, L. Parisi, M. Palmery, A. Meneguz and L. Tomassini. In vitro relaxant and spasmolytic effects of constituents from *Viburnum prunifolium* and HPLC quantification of the bioactive isolated iridoids. *Journal of Ethnopharmacology* 123: 201-207(2009).

P. Popoli, M.F. Cometa, F. Fabi, A. Meneguz. The role of the Istituto Superiore di Sanità as the competent authority for Phase I trials in the translation of advanced therapies. *Annali Istituto Superiore Sanità* 47(1): 79-82L (2011).

MF Cometa, S Fortuna, G Palazzino, MT Volpe, E Rengifo Salgado, M Nicoletti, L.Tomassini New cholinesterase inhibiting bisbenzylisoquinoline alkaloids from *Abuta grandifolia*. *Fitoterapia* Apr;83(3):476-80 (2012).

A. Venerosi, S. Tait, L. Stecca, F. Chiarotti, A. De Felice, M.F. Cometa,

M. T. Volpe, G. Calamandrei and L. Ricceri. Effects of maternal chlorpyrifos diet on social investigation and brain neuroendocrine markers in the offspring: a mouse study. *Environmental Health* 14:32 (2015)

Tomassini L, Serafini M, Ventrone A, Nicoletti M, Cometa MF, Ragusa S. A new iridoid diglycoside from *Antirrhinum siculum*. *Nat Prod Res.* (2017) Jul;31(14):1594-1597. doi: 10.1080/14786419.2017

Tomassini L, Ventrone A, Frezza C, Serafini I, Bianco A, Cometa MF. Lignans and secoiridoid glycosides from the stem barks of *Jasminum tortuosum*. *Nat Prod Res.* (2017) Nov 15:1-5. doi: 10.1080/14786419.2017

Tomassini L, Ventrone A, Frezza C & Cometa MF. A new iridoid diglycoside from *Sambucus ebulus* L. *Nat Prod Res.* (2019) Feb 27:1-7. doi: 10.1080/14786419.2019.1577836.

Other publications

Monograph of America Herbal Pharmacopoeia Cometa MF Reviewer and Author-Black Haw Bark
Viburnum prunifolium- Analytical, quality control, and therapeutic Monograph of America Herbal
Pharmacopoeia and therapeutic Compendium. Ed. Roy Upton Herbalist, Santa Cruz, USA June
2000 pp1-17

M.F.Cometa e L.Gagliardi. Compiti dell'Istituto Superiore di Sanità e aspetti critici nella valutazione
della sicurezza dei prodotti cosmetici contenenti sostanze naturali- Natural1 Novembre 2008-ANNO
VIII- N°77.pp 42-45

M.F.Cometa Prodotti di natura Vegetale in Italia e nella Comunità europea: aspetti normativi.
Rapporti ISTISAN (2008) 08/41, pp 91-108.

A. Meneguz, MF Cometa Verso una revisione della Direttiva 2001/20 e una maggiore
armonizzazione europea dei trial clinici precoci. In .Rapporti ISTISAN: 12/37Attività e impegno
dell'Istituto Superiore di Sanità nella lotta contro il cancro. 2012

MF Cometa, Bonetto. Le norme di Buona Pratica di Laboratorio Sperimentazione e registrazione dei
radio farmaci Normative e procedure-Springer ED 2013, A cura di Lucignani, Nicotra e Meneguz-
Pagg 85-94

I Sestili, G Gostoli, F. Fabi, MF Cometa. La preparazione di un Investigational Medicinal Product
Dossier (IMPD)- Sperimentazione e registrazione dei radio farmaci Normative e procedure-Springer
ED 2013, A cura di Lucignani, Nicotra e Meneguz- Pagg 105-123

D Taruscio, L.Bertinato, P.Caprari, M.De Santis, R.I.Romeo, M.F.Cometa, A.Magrelli,P.
Popoli-Interim guidance for the appropriate support of people with enzymopenia G6PD (favism) in
the current SARS-CoV-2 emergency scenario. Version April 14, 2020.ISS COVID-19 Rare Diseases
Working Group

2020, 9 p. Rapporti ISS COVID-19 n. 14/2020

M.F.Cometa, G.Di Felice, F. Menniti Ippolito, I. Ippolito, P.Popoli, C. Boniglia, M.Silano, L.
Bertinato-Food supplements or drugs? Regulations and recommendations for conscious use in time
of COVID-19. Version of May 31, 2020.ISS Working Group Drugs COVID-19 2020, ii, 29 p.
Rapporto ISS COVID-19 n. 51/2020

Projects

Memberships

Other Relevant Information

Number of IMPD Assessment:440

Number of evaluation of preclinical experimental models according to the Directives of the Council of
the European Communities (2010/63/EU ex 86/609/CEE) on animal care: 620

Number of non clinical evaluation of medicinal herbal (National registration) and assessment on
cosmetic/medical devices/dietary supplement containing herbal substances:43

Number of Non Clinical Assessment Report for European Procedures (Centralised, Decentralised,
Mutual Recognition) and national procedures: 36

Number of GLP inspection:31