

Curriculum Vitae

Personal information **Maria Francesca Cometa**

Work experience

1. Employer: Istituto Superiore di Sanità (Italian National Public Health Institute)
 - Start date: 2001
 - End date:
 - Position: Researcher_ Expert for toxicological aspects of preclinical test
 - Activities:
 - Evaluation of the dossier for preclinical test required to the Phase I trial authorization of drug in relation to the Law by Decree n° 439/2001
 - Phase I IMPD dossier evaluation
2. Employer: Istituto Superiore di Sanità
 - Country: Italy
 - Start date: 2001
 - End date:
 - Position: Researcher_ Expert for toxicological aspects of preclinical test
 - Activities:
 - Expert to evaluation preclinical experimental models according to the Directives of the Council of the European Communities (86/609/EEC) on animal care
2. Employer: Ministry of Health
 - Country: Italy
 - Start date: 2002
 - End date: 2012
 - Position: Junior GLP inspector
 - Activities:
 - 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)
3. Employer: Istituto Superiore di Sanità
 - Country: Italy
 - Start date: 2003
 - End date:
 - Position: Researcher_ Expert for toxicological aspects of preclinical test
 - Activities:
 - 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
4. Employer: Istituto Superiore di Sanità
 - Country: Italy
 - Start date: 2004
 - End date:
 - Position: Researcher_ Expert for toxicological aspects of preclinical test
 - Activities:
 - Preclinical Assessor for Centralised, Decentralised and Mutual recognition procedures
 - Preclinical Assessor for National Authorization of herbal medicinal product
5. Employer: Faculty of Pharmacy, University "La Sapienza", Rome
 - Country: Italy
 - Start date: 2004
 - End date:
 - Position: Researcher_ Expert for toxicological aspects of preclinical test
 - Activities:
 - Teaching contract for University in:
 - General Toxicology
 - Pharmacological and toxicological methods in herbal science
 - University teaching and experimental degree thesis advisor
6. Employer: AIFA (Italian Medicines Agency)
 - Country: Italy
 - Start date: october 2006
 - End date: october 2006
 - Position: Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization

- Activities: Annual Preclinical Assessor Meeting
 - Country: Italy
7. Employer: Istituto Superiore di Sanità
- Start date: 2008
 - End date:
 - Position: Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization
 - Activities:

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

- Country: Italy
8. Employer: Istituto Superiore di Sanità
- Start date: 2008
 - End date:
 - Position: Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization
 - Activities:

Teaching in courses for University Masters in Clinical Trials

- Country: Italy
9. Employer: Istituto Nazionale Per lo studio e la cura dei tumori
- Start date: december 2008
 - End date: december 2008
 - Position: Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization
 - Activities:

Updating course in biological therapy for tumors: Scientific and Regulating aspect

- Country: Italy
2. Employer: Istituto Superiore di Sanità
- Start date: 2009
 - End date:
 - Position: Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization
 - Activities:

Teaching in national and international meeting on Phase I Clinical Trial

- Country: Italy
3. Employer: Istituto Internazionale di Ricerca
- Start date: 2009
 - End date: 2011
 - Position: Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization
 - Activities:

Meeting on Phase I Clinical Trial

- Country: Italy
2. Employer: Istituto Superiore di Sanità
- Start date: 2010
 - End date:
 - Position: Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization
 - Activities:

Teaching in courses for Assessors involved in the evaluation of dossier (Investigational Medicinal Product Dossier, Investigator's Brochure and Clinical Protocol) of phase I Clinical Trial Application

- Country: Italy
3. Employer: Ministry of Health
- Start date: 2012
 - End date:
 - Position: Senior/Coordinator GLP Inspector
 - Activities:

Performing GLP inspections (reports)

- Country: Italy
4. Employer: Istituto Superiore di Sanità
- Start date: 2013
 - End date: 2013
 - Position: Member of Scientific Secretariat of Italian Competent Authority for Phase I Clinical Trial Authorization
 - Activities:

Course on translational application for investigational ATMPs (Advanced Therapy Medicinal Products)

- Country: Italy
2. Employer: Istituto Superiore di Sanità
- Start date: 2015
 - End date:
 - Position: Researcher
 - Activities:

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.

- Country: Italy
2. Employer: Ministry of Health
- Start date: 2018
 - End date:
 - Position: Secretary of Phase I clinical trial Committee
 - Activities:

Scientific technical activity for the committee

- Country: Italy
2. Employer: EMA/AIFA
- Start date: 2018
 - End date:
 - Position: Italian delegate
 - Activities:

EMA GLP Inspectors Working Group

- Country: Italy
2. Employer: Istituto Superiore di Sanità
- Start date: 2018
 - End date:
 - Position: Head of Unit of Preclinical and Clinical evaluation of medicinal drugs
 - Activities:

Regulatory affairs Non clinical and clinical assessor Committee for Phase I clinical trial in Italy/Scientific secretary coordinator

- Country: Italy

Education and training

1. Subject: Laboratory of Phytochemicals, Faculty of Pharmacy, University "La Sapienza"
 - Start date: 1989
 - End date: 1991
 - Qualification: Guest worker for phytochemical studies on medicinal plants
 - Organisation: phytochemistry and pharmacognosy
 - Country: Italy
2. Subject: Laboratory of Phytochemicals, Faculty of Pharmacy, University "La Sapienza"
 - Start date: 07.1991
 - End date:
 - Qualification: Degree in pharmacy (summa cum laude)
 - Organisation: phytochemistry and pharmacognosy
 - Country: Italy
3. Subject: Department of Pharmacology of Natural Substances and General Physiology, Faculty of Pharmacy, University "La Sapienza"
 - Start date: 1993
 - End date: 1997
 - Qualification: PhD in Pharmacology, Pharmacognosy and Toxicology
 - Organisation:
 - Country: Italy
4. Subject: Faculty of Pharmacy, Universidad Catolica del Peru _ Lima _ Peru
 - Start date: 03.1994
 - End date: 04.1994
 - Qualification: Visiting scientist
 - Organisation: phytochemistry and pharmacognosy
 - Country: Peru
5. Subject: Faculty of Biology, Botanical Institute and Garden, Studentski trg 6, 11000 Belgrade
 - Start date: 03.1995
 - End date: 04.1995
 - Qualification: Visiting Scientist
 - Organisation: phytochemistry and pharmacognosy
 - Country: Serbia
6. Subject: Department of Pharmacology of Natural Substances and General Physiology, Faculty of Pharmacy, University "La Sapienza"
 - Start date: 1997
 - End date: 2000
 - Qualification: Postgraduate Research Fellowship
 - Organisation: phytochemistry and pharmacognosy
 - Country: Italy
7. Subject: Department of Pharmacology of Natural Substances and General Physiology, Faculty of Pharmacy, University "La Sapienza"
 - Start date: 2000
 - End date: 2001
 - Qualification: Research grant in Pharmacognostic Science
 - Organisation: phytochemistry and pharmacognosy
 - Country: Italy
8. Subject: Section of Biochemical Pharmacology and Technical Scientific Advice Coordination Unit, Department of Therapeutic Research and Medicines Evaluation_ Istituto Superiore di Sanità
 - Start date: 2001
 - End date:
 - Qualification: Confirmed Researcher
 - Organisation:
 - Country: Italy
9. Subject: Ministry of Health
 - Start date: 2002
 - End date: 2016
 - Qualification: Toxicology expert
 - Organisation:
 - Country: Italy
10. Subject: Istituto Superiore di Sanità
 - Start date: 2003
 - End date: 2003
 - Qualification: Update on the issues for authorization of animal use in preclinical test
 - Organisation:
 - Country: Italy
11. Subject: BfArM (Federal Institute for Drugs and Medical Devices)
 - Start date: 10.2004
 - End date: 10.2004
 - Qualification: Update on the issues for the nonclinical assessment of dossiers for EMEA
 - Organisation:
 - Country: Germany
12. Subject: HESI (ILSI Health and Environmental Science Institute)
 - Start date: 11.2005

- End date: 11.2005
 - Qualification: Update on the issues for the nonclinical assessment of dossiers for EMEA
 - Organisation:
 - Country:
13. Subject: Charles River
- Start date: 12.2008
 - End date: 12.2008
 - Qualification: Update on the issues for the nonclinical assessment of dossiers for Competent Authority (Phase I clinical trial) and EMEA
 - Organisation:
 - Country: United Kingdom

Additional information

Publications

Main Scientific publication (1993_2024):

- [M.F. Cometa](#), L. Tomassini, M. Nicoletti, S. Pieretti. "Phenylpropanoid glycosides. Distribution and pharmacological activity". *Fitoterapia* vol. LXIV (3): 195-217 (1993).
- L. Tomassini, [M.F. Cometa](#), S. Foddai, M. Nicoletti. "Iridoid Glucosides from *Viburnum tinus*". *Phytochemistry*, 38: 423-425 (1995).
- L. Tomassini, [M.F. Cometa](#), M. Serafini, M. Nicoletti. "Isolation of secoiridoid artifacts from *Lonicera japonica*". *Journal of Natural Products*, 58 (11): 1756-1758 (1995).
- [M.F. Cometa](#), C. Galeffi, M. Palmery. "Acute effect of alkaloids from *Hydrastis canadensis* L. on guinea-pig ileum: Structure-Activity Relationships". *Phytotherapy Research* 10: S56-58 (1996).
- M. Palmery, [M.F. Cometa](#), M.G. Leone. "Further studies of the adrenolytic activity of the major alkaloids from *Hydrastis canadensis* L. on isolated rabbit aorta". *Phytotherapy Research* 10: S47-4 (1996).
- M.G. Leone, [M.F. Cometa](#), M. Palmery, L. Saso. "HPLC Determination of the major alkaloids extracted from *Hydrastis canadensis* L." *Phytotherapy Research* 10: S45-46 (1996).
- C. Galeffi, [M.F. Cometa](#), L. Tomassini, M. Nicoletti. "Canadinic acid: an alkaloid from *Hydrastis canadensis*". *Planta Medica* 63: 194 (1997).
- L. Tomassini, S. Foddai, M. Nicoletti, [M.F. Cometa](#), G. Palazzino, C. Galeffi. "Iridoid Glucosides from *Viburnum ayavacense*". *Phytochemistry* 46 (5): 901-905 (1997)
- [M.F. Cometa](#), G. Mazzanti, L. Tomassini. "Sedative and spasmolytic effects of *Viburnum tinus* L. and its major pure compounds". *Phytotherapy Research* 12: S89-91 (1998).
- P. Bolle, [M.F. Cometa](#), P. Palmery and P. Tucci. "Response of rabbit detrusor muscle to total extract and major alkaloids of *Hydrastis canadensis*". *Phytotherapy Research* 12: S86-88 (1998).
- [M.F. Cometa](#), H. Abdel-Haq, M. Palmery. "Spasmolytic activities of *Hydrastis canadensis* L. on rat uterus and guinea-pig trachea". *Phytotherapy Research* 12: S83-85 (1998).
- L. Tomassini, [M.F. Cometa](#), S. Foddai and M. Nicoletti. "Iridoid Glucosides from *Viburnum prunifolium*". *Planta Medica* 65: 195 (1999).
- L. Tomassini, S. Foddai, M. Serafini and [M.F. Cometa](#). Bis-iridoid "Glucosides from *Abelia chinensis*". *Journal of Natural Products* 63 (7): 998-999 (2000).
- G. Palazzino, C. Galeffi, E. Federici, F. Delle Monache, [M.F. Cometa](#), M. Palmery "Benzylbenzoate and norlignan glucosides from *Curculigo pilosa*: structural analysis and *in vitro* vascular activity". *Phytochemistry* 55: 411-417 (2000).
- H. Abdel-Haq, [M.F. Cometa](#), M. Palmery, M.G. Leone, L. Saso and B. Silvestrini. "Relaxant effects of *Hydrastis canadensis* L. and its major alkaloids on guinea-pig isolated trachea". *Pharmacology and Toxicology* 87: 218-222 (2000).
- F. Scazzocchio, [M.F. Cometa](#), L. Tomassini, M. Palmery. "Antimicrobial Activity of *Hydrastis canadensis* Extract and its Major Isolated Alkaloids". *Planta Medica* 67: 561-564 (2001).
- [M.F. Cometa](#), G. Palazzino, C. Galeffi, M. Palmery. "Studies on vasoconstrictor activity of *Curculigo pilosa* extracts and of its isolated compounds". *Il Farmaco* 56: 353-356 (2001).
- Luzi, [M.F. Cometa](#), M. Palmery. "Acute effects of aflatoxins on guinea pig isolated ileum". *Toxicology in vitro* 16: 525-529 (2002).
- 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).
- [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 in 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 P, [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". [Ann Ist Super Sanita](#).47(1):79-82 (2011).
- [M.F. 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).
- Venerosi, S. Tait, L. Stecca, F. Chiarotti, A. De Felice, [M. F. Cometa](#), M. T. Volpe, G. Calamandrei e L. Ricceri "Effects of maternal chlorpyrifos diet on social investigation and brain neuroendocrine markers in the offspring – a mouse study". *Environmental Health* Apr 2;14: 32 (2015) -DOI 10.1186/s12940-015-0019-6
- L. Tomassini, M. Serafini, A. Ventrone, M. Nicoletti, [M.F. Cometa](#), S. Ragusa. "A new iridoid diglucoside from *Antirrhinum siculum*". *Nat. Prod.Res.* Jul; 31(14):1594-1597 (2017). DOI: 10.1080/14786419.2017.1286482
- L. Tomassini, A. Ventrone, C. Frezza, I. Serafini, A. Bianco, [M.F. Cometa](#). "Lignans and secoiridoid glycosides from the stem barks of *Jasminum tortuosum*". *Natural Product Research*, **32 (15)**: 1853-1857 (2018). DOI: 10.1080/14786419.2017.1404597
- L. Tomassini, A. Ventrone, C. Frezza & [M.F. Cometa](#). "A new iridoid diglycoside from *Sambucus ebulus* L." *Natural Product Research*, **34(15)**, 2137-2143 (2020). DOI: 10.1080/14786419.2019.1577836
- L. Tomassini, A. Ventrone, C. Frezza, A. M. Fabbri, S. Fortuna, M. T. Volpe & [M.F. Cometa](#). "Phytochemical analysis of *Viburnum davidii* Franch and cholinesterase inhibitory activity of its dihydrochalcones". *Natural Product Research* Dec;35(24):5794-5800 (2021)DOI: 10.1080/14786419.2020.1837814 Epub 2020 Oct 23.
- S.Bellino, A.La Salvia, M.F. Cometa, R. Botta "Cell-based medicinal products approved in the European Union: current evidence and perspectives"-Front Pharmacol 2023 Jul 31:14:1200808. doi: 10.3389/fphar.2023.1200808
- L. Giorgioni, A. Ambrosone, M.F. Cometa, A.L. Salvati, A.Magrelli "CAR-T State of the Art and Future Challenges, A Regulatory Perspective" Int J Mol Sci . 2023 Jul 22;24(14):11803. doi:

10.3390/ijms241411803.

- [L. Giorgioni, A. Ambrosone, M.F. Cometa, A.L. Salvati](#), R. Nisticò, [A. Magrelli](#) "Revolutionizing CAR T-Cell Therapies: Innovations in Genetic Engineering and Manufacturing to Enhance Efficacy and Accessibility " Int. J. Mol. Sci. 2024, 25(19), 10365; <https://doi.org/10.3390/ijms251910365>

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. Ippoliti, 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 M.F. Cometa, P. Popoli_ Il ruolo dell'Istituto Superiore di Sanità nella valutazione delle richieste di ammissibilità alla sperimentazione clinica di Fase I_ I Manuali SIFO_ Il farmacista di ricerca e il farmacista ricercatore_ pp 84_96. Edizioni Il Campano (2022). 16° Rapporto sulla Condizione assistenziale dei malati oncologici- 2024- I Quaderni di Quotidiano sanità.it 46- a cura di F. Perrone, G. Curigliano, [M.F. Cometa](#), D. Gramaglia, F. Galliccia, C. Pinto "Le potenzialità degli Studi di Fase I: a che punto siamo e quali criticità per l'accesso in Italia"pp37-43

Projects

Responsible for 4 Funded Research Projects under ISS Current Research (from 2006 to 2009). Collaborator in Funded Research Projects: -Extraordinary Oncology Research Program 2006. Alliance Against Cancer (ACC)- Istituto Superiore di Sanità (art.3 DM July 21, 2006) Program 2 "Integration of research activities through the construction of inter-institutional collaborative structures and networks".Project title: Regulatory support activities, review of the national and European regulatory regulatory scenario and implementation of Consensus Documents and Conference

Memberships

EMA GLP Inspectors Working Group - Italian Member

Expert of the Italian Permanent Working Group for the protection of animals used for scientific purposes of the Ministry of Health- (Sezione IV Consiglio Superiore di sanità)

Other Relevant Information

Number of IMPD Assessment: 1475.

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: 640

Number of non clinical evaluation of medicinal herbal (National registration) and assessment on cosmetic/medical devices/dietary supplement containing herbal substances: 42

Number of Non Clinical Assessment Report for European Procedures (Centralised, Decentralised, Mutual Recognition) and national procedures: 26.

Number of GLP inspection:43