

Curriculum Vitae

Personal information **Laura Campitelli**

Work experience

1. Employer: Istituto Superiore di Sanità'
 - Start date: 012023
 - End date:
 - Position: Research Manager
 - Activities:
 - Coordinator of the Viral Vaccines Unit activities of the Italian OMCL. They include quality control of Viral vaccines and research activities on methods development
 - Quality assessor for the evaluation of the quality part of licensing and post_licensure dossiers of biotechnological products, including vaccines, within the National and Centralised procedures.
 - Member of the European Pharmacopea Group 15 on human vaccines and sera for the elaboration/revision of chapters and monographs on vaccines for human use
 - Member of the mRNAC working party of the European Pharmacopea, for the elaboration of chapters and monographs on mRNA vaccines.
 - Member of the OCABR Vaccine Drafting Group of the OMCL Network
 - Country: Italy
2. Employer: Istituto Superiore di Sanità
 - Start date: 042020
 - End date: 122022
 - Position: Staff Senior scientist
 - Activities: Deputy coordinator of the Viral Vaccines Unit of the Italian OMCL, dealing with the Batch Release of vaccines for the European Market area Quality assessor for the evaluation of the quality part of licensing and post_licensure dossiers within the National and Centralised procedures. Expert of the European Medicine Agency for the quality part of biological products. Research activities concerning the development of in vitro potency assays for human vaccines
 - Country: Italy
3. Employer: Istituto Superiore di Sanità'
 - Start date: 022018
 - End date: 032020
 - Position: Seconded National Expert at the European Medicines Agency
 - Activities: Scientific officer at the Quality Office of EMA. Scientific support to the Biologics/Biotech Working Party (BWP). Involved in the activities concerning scientific advice and marketing authorization applications of biological medicinal products, including vaccines, recombinant products, ATMPs, as regards the quality aspects of applications.
 - Country: Italy
4. Employer: National Centre for the Control and Evaluation of Medicines (CNCF), Istituto Superiore di Sanità
 - Start date: 052008
 - End date: 012018
 - Position: Staff senior scientist
 - Activities:

Head of the Influenza vaccine Unit:

1. Responsible for the Batch Release of influenza vaccines for the Italian and European market.
2. Quality assessor for the evaluation of licensing and post_licensure dossiers within the National, Mutual Recognition, Centralised and Decentralised procedures
3. Expert of the European Medicine Agency for influenza vaccines evaluation
4. Member of the BWP Drafting Group for the revision of the quality part of the European guideline on influenza vaccines.

Research activities on the correlates of protection from influenza infection, and on the development of potency testing assays in human and veterinary vaccines, including participation in an IMI2 project on the development of alternative in vitro potency assays for human and veterinary vaccines (see projects section below)

5. Employer: Istituto Superiore di Sanità, Rome, Italy
 - Start date: 011990
 - End date: 042008
 - Position: Staff scientist
 - Activities:
 - Deputy responsible for the Batch Release of influenza vaccines for the Italian and European market.
 - Set up and standardization of tests used for the batch release of vaccines, including LAL test (for the detection of bacterial endotoxins according to Ph.Eur), and PAGE (to evaluate vaccine

purity), and compilation of the relevant SOPs

- Quality assessor for the evaluation of vaccine licensing dossiers within the Mutual Recognition Procedures
- Surveillance of the circulation of influenza viruses in humans, and standardisation of techniques for rapid diagnosis of influenza in clinical samples.
- Studies on the ecology of influenza viruses: virological surveillance in non_human hosts (such as pigs, birds and horses), and their role in interspecies transmission
- Studies on the molecular mechanisms of the emergence of new human (and potentially pandemic) influenza viruses from animal sources
- Studies on the molecular evolution of influenza viruses in animals and humans.

Preparation of the Italian Influenza Pandemic Plan

- Country: Italy
6. Employer: Istituto Superiore di Sanità
- Start date: 051987
 - End date: 011990
 - Position: Post doctoral position
 - Activities:

Molecular characterization of influenza viruses.

Surveillance studies on influenza circulation in Italy.

Influenza vaccine batch release testing.

- Country: Italy

Education and training

1. Subject: Dept. Virology and Molecular Biology, St. Jude Children's Research Hospital
- Start date: 091995
 - End date: 121995
 - Qualification: Visiting scientist
 - Organisation:

Molecular biology techniques for studying the ecology of influenza viruses in non_human hosts

- Country: United States
2. Subject: Dept. Virology and Molecular Biology, St. Jude Children's Research Hospital
- Start date: 101996
 - End date: 021997
 - Qualification: Visiting scientist
 - Organisation:

Molecular biology techniques for studying the ecology of influenza viruses in non_human hosts

- Country: Italy
3. Subject: National Institute for Biological Standards and Controls
- Start date: 041992
 - End date: 051992
 - Qualification: Training in molecular biology techniques
 - Organisation:

Molecular biology techniques for studying virus replication and their biological features

- Country: United Kingdom
4. Subject: University of Rome "la Sapienza"
- Start date: 111981
 - End date: 031987
 - Qualification: Master's Degree in Biological Sciences
 - Organisation:
 - Virology and Microbiology
 - biochemistry
 - Final thesis " Five years of virological Surveillance of influenza viruses in Italy"
 - Country: Italy

Additional information

Publications

- 1) Mancini G., Arangio_Ruiz G., **Campitelli L.**, Castrucci M.R., Diana L., Donatelli I., Ruggieri A. (1988). Surveillance of influenza A and B viruses in Italy between 1984 and 1987. Eur. J. Epidemiol., 4: 445_50.
- 2) Donatelli I., Mancini G., Castrucci M.R., **Campitelli L.**, Corcoran T., Yates P., Oxford J.S. (1989). Protein and nucleic acid analysis of influenza B viruses isolated in Italy in 1984. J. Med. Virol., 27: 201_9.
- 3) Mancini G., Arangio_Ruiz G., Bianchi B., Diana L., Macchia T., Donatelli I., Castrucci M.R., **Campitelli L.**, Ruggieri A. (1989). Influenza vaccination in elderly residents in nursing homes: immune response to trivalent and monovalent inactivated influenza virus vaccine in the season 1986_87. Eur. J. Epidemiol., 5: 214_8.
- 4) Donatelli I., **Campitelli L.**, Castrucci M.R., Madonna E. (1990) Persistence and evolution of human influenza viruses in non_human hosts. J. Prev. Med. Hyg. 31: 5_9
- 5) Donatelli I., Castrucci M.R., **Campitelli L.**, Ruggieri A., Sidoli L., Buonavoglia C. (1991). First recovery of A/equine/Fontainebleau/1/79 influenza viruses in Italy. Comp. Immunol. Microbiol. Infect. Dis., 14: 315_23.
- 6) Donatelli I., **Campitelli L.**, Castrucci M.R., Ruggieri A., Sidoli L., Oxford J.S. (1991). Detection of two antigenic subpopulations of A(H1N1) influenza viruses from pigs: antigenic drift or interspecies transmission? J. Med. Virol., 34: 248_57.
- 7) Iorio A.M., Zei T., Neri M., **Campitelli L.**, Castrucci M.R., Donatelli I. (1992). Immunization of elderly volunteers

with the 1988_89 inactivated whole influenza vaccine: assessment of antibody responses by haemagglutination inhibition and single radial haemolysis tests. Eur. J. Epidemiol., 8: 491_7.

8) Donatelli I., **Campitelli L.**, Ruggieri A., Castrucci M.R., Calzoletti L., Oxford J.S. (1993). Concurrent antigenic analysis of recent epidemic influenza A and B viruses and quantitation of antibodies in population serosurveys in Italy. Eur. J. Epidemiol., 9: 241_50.

9) Castrucci M.R., **Campitelli L.**, Ruggieri A., Barigazzi G., Sidoli L., Daniels R., Oxford J.S., Donatelli I. (1994). Antigenic and sequence analysis of H3 influenza virus haemagglutinins from pigs in Italy. J. Gen. Virol., 75: 371_9.

10) Nardelli L., Donatelli I., Castrucci M.R., **Campitelli L.**, Sidoli L. (1994). Storiadei rapporti fra influenza suina ed influenza umana. L'Igiene Moderna, 102:751_76.

11) **Campitelli L.**, Donatelli I., Foni E., Castrucci M.R., Fabiani C., Kawaoka Y., Krauss S., Webster R.G. (1997). Continued evolution of H1N1 and H3N2 influenza viruses in pigs in Italy. Virology, 232: 310_8.

12) Donatelli I., **Campitelli L.**, Fabiani C. (1997). La problematica dei vaccini antinfluenzali in funzione della variabilità dei virus. Professione, 5: 15_22.

13) De Marco M.A., Foni E., Guberti V., Raffini E., Donatelli I., Barigazzi G., **Campitelli L.**, Delogu M., Govoni S. (1997). Influenza aviaria: indagine sierologica e isolamento virali in uccelli acquatici catturati in aree protette della Toscana. La Selezione Veterinaria, 8_9: 811_7.

14) Donatelli I., **Campitelli L.** (1998). Variabilità dei virus influenzali e profilassi dell'influenza. In: "Vaccinare oggi". Numero Speciale: 1_11. Gruppo Editoriale Editeam, Bologna.

15) **Campitelli L.**, Mogavero E., De Marco M.A., Delogu M., Puzelli S., Frezza F., Facchini M., Foni E., Chiapponi C., Cordioli P., Webby R., Barigazzi G., Webster R.G., Donatelli I. (2004) Interspecies transmission of H7N3 influenza virus from wild birds to intensively reared domestic poultry in Italy, Virology, May 20;323(1):24_36

16) Salmaso S., Bella A., De Mei B., Giannitelli S., Mandolini D., Rota M.C., Donatelli I., Affinito C., **L. Campitelli L.**, Fabiani C., Frezza F., Fiaccavento S., Puzelli S. (GRUPPO FLU_ISS) (2001). "FLU_ISS: Sistema di sorveglianza sentinella dell'influenza basata su medici di medicina generale e pediatri di libera scelta. Rapporto finale sulla stagione influenzale 2001_2002", 92 p. Rapporti ISTISAN 02/19.

17) Puzelli S., Frezza F., Fabiani C., Ansaldi F., **Campitelli L.**, Lin Y.P., Gregory V., Bennett, D'Agaro P., Campello C., Crovari C., Hay A., Donatelli I. (2004) Changes in Hemagglutinin and neuraminidases of human influenza B viruses isolated in Italy during the 2001_02, 2002_03 and 2003_04 seasons. J. Med. Virol. 74:626_640 (2004)

18) Puzelli S., Di Trani L., Fabiani C., **Campitelli L.**, De Marco M.A., Aguilera J.F., Zambon M., Donatelli I. (2005) Serological analysis of humans exposed to avian H7 influenza viruses in Italy between 1999 and 2003. J. Infect. Dis. 192(8):1318_22.

19) Puzelli S., Di Trani L., Fabiani C., **Campitelli L.**, De Marco M.A., Aguilera J.F., Zambon M., Donatelli I. (2006) Reply to Skowronski et al. Human Illness and Isolation of Low Pathogenicity Avian Influenza Virus of the H7N3 Subtype in British Columbia, Canada. J. Infect. Dis. 193:900_01

20) De Marco M.A., Foni E., **Campitelli L.**, Delogu M., Raffini E., Chiapponi C., Barigazzi G., Cordioli P., Di Trani L., Donatelli I. (2005) Influenza virus circulation in wild aquatic birds in Italy during H5N2 and H7N1 poultry epidemic periods (1998 to 2000). Avian Pathol. 34(6):480_5.

21) Salmaso S., Bella A., Corridi P., D'Ancona F.P., De Mei B., Giannitelli S., Mandolini D., Rota M.C., Donatelli I., Affinito C., **Campitelli L.**, Fabiani C., Fiaccavento S., Puzelli S. (GRUPPO FLU_ISS) (2000) "FLU_ISS: Sistema di sorveglianza sentinella dell'influenza basata su medici di medicina generale e pediatri di libera scelta", 75 p. Rapporti ISTISAN 00/21

22) Donatelli I., **Campitelli L.**, Puzelli S., Affinito C., Fabiani C., Fiaccavento S. (2000). Sorveglianza dell'influenza in Italia. Notiziario dell'Istituto Superiore di Sanità, 13: 1_5.

23) Salmaso S., Donatelli I., Crovari P., and Collaborative Groups for Influenza Surveillance. (2000). The Italian network for surveillance of influenza, 1999_2000. J. Preventive Med. Hygiene 41:59_61.

24) Donatelli I., **Campitelli L.**, Puzelli S., Fabiani B., Affinito C., Fiaccavento S. (2000). Piano Nazionale di Emergenza in Caso di Pandemia Influenzale e Programma di Sorveglianza dell'Influenza. In: "Influenza" (E. Altomare Ed.). Avverbi Edizioni, pp. 153_63.

25) Donatelli I., **Campitelli L.**, Di Trani L., Puzelli S., Selli L., Fioretti A., Alexander D.J., Tollis M., Krauss S., Webster R.G. (2001). Characterization of H5N2 influenza viruses from Italian poultry. J. Gen. Virol., 82: 623_30.

26) Donatelli I., C. Affinito, F. Beneduce, L. Calzoletti, **L. Campitelli**, C. Fabiani, S. Fiaccavento, S. Puzelli (2001). Centro Nazionale Influenza: sorveglianza virologica dell'influenza in Italia. Rapporto preliminare, 22 p. Rapporti ISTISAN 01/9.

27) Salmaso S., Bella A., De Mei B., Giannitelli S., Mandolini D., Rota M.C., Donatelli I., Affinito C., **Campitelli L.**, Fabiani C., Fiaccavento S., Puzelli S. (GRUPPO FLU_ISS) (2001). "La sorveglianza dell'influenza in Italia nella stagione 2000_2001" Notiziario dell'Istituto Superiore di Sanità, Marzo, vol. 14 n. 3.

28) Salmaso S., Bella A., De Mei B., Giannitelli S., Mandolini D., Rota M.C., Donatelli I., Affinito C., Beneduce F., Calzoletti L., **Campitelli L.**, Fabiani C., Fiaccavento S., Puzelli S. (GRUPPO FLU_ISS) (2001). "FLU_ISS: Sistema di sorveglianza sentinella dell'influenza basata su medici di medicina generale e pediatri di libera scelta. Rapporto finale sulla stagione influenzale 2000_2001", 89 p. Rapporti ISTISAN 01/14.

29) **Campitelli L.**, Fabiani C., Puzelli S., Fioretti A., Foni E., De Marco A., Krauss S., Webster R.G., Donatelli I. (2002). H3N2 Influenza viruses from domestic chickens in Italy: an increasing role for chickens in the ecology of influenza? J. Gen. Virol. 83:413_20.

30) De Marco M.A., Foni E., **Campitelli L.**, Raffini E., Delogu M. and Donatelli I., (2003) Long term Monitoring for Avian influenza viruses in wild bird species in Italy, Veterinary Research Communication, 27 Suppl., 1, 107_114

31) Delogu M., De Marco M.A., Donatelli I., **Campitelli L.** and Catelli E., (2003) Ecological Aspects of influenza A virus Circulation in wild birds of western Palearctic, Veterinary Research Communication, 27 Suppl., 1, 101_106

32) Donatelli I., **Campitelli L.**, Puzelli S., Affinito C., De Marco M.A., Delogu M. and Barigazzi G., (2003) Influenza viruses: structure and interspecies transmission mechanism, Veterinary Research Communication, 27 Suppl., 1, 115_122

33) De Marco M.A., Foni E., **Campitelli L.**, Raffini E., Di Trani L., Delogu M., Guberti V., Barigazzi G. and Donatelli I. (2003) Circulation of Influenza viruses in wild waterfowl wintering in Italy during the 1993 - 1999 period: evidence of virus shedding and seroconversion in wild ducks, Avian Diseases 47:861_866

- 34) De Marco M.A., **Campitelli L.**, Foni E., Raffini E., Barigazzi G., Delogu M., Guberti V., Di Trani L., Tollis M. and Donatelli I. (2003). Influenza Surveillance in birds in Italian wetlands (1992_1998): is there a host restricted circulation of influenzaviruses in sympatric ducks and coots? *Vet. Microbiol. J.*, 98: 197_208.
- 35) **Campitelli L.**, Mogavero E., De Marco M.A., Delogu M., Puzelli S., Frezza F., Facchini M., Foni E., Chiapponi C., Cordioli P., Webby R., Barigazzi G., Webster R.G., Donatelli I. (2004) Interspecies transmission of H7N3 influenza virus from wild birds to intensively reared domestic poultry in Italy, *Virology*, May 20;323(1):24_36
- 36) Salmaso S., Bella A., De Mei B., Giannitelli S., Mandolini D., Rota M.C., Donatelli I., Affinito C., L., **Campitelli L.**, Fabiani C., Frezza F., Fiaccavento S., Puzelli S. (GRUPPO FLU_ISS) (2001). "FLU_ISS: Sistema di sorveglianza sentinella dell'influenza basata su medici di medicina generale e pediatri di libera scelta. Rapporto finale sulla stagione influenzale 2001_2002", 92 p. Rapporti ISTISAN 02/19.
- 37) Puzelli S., Frezza F., Fabiani C., Ansaldo F., **Campitelli L.**, Lin Y.P., Gregory V., Bennett., D'Agaro P., Campello C., Crovari C., Hay A., Donatelli I. (2004) Changes in Hemagglutinin and neuraminidases of human influenza B viruses isolated in Italy during the 2001_02, 2002_03 and 2003_04 seasons. *J. Med. Virol.* 74:626_640 (2004)
- 38) Puzelli S., Di Trani L., Fabiani C., **Campitelli L.**, De Marco M.A., Aguilera J.F., Zambon M., Donatelli I. (2005) Serological analysis of humans exposed to avian H7 influenza viruses in Italy between 1999 and 2003. *J. Infect. Dis.* 192(8):1318_22
- 40) Puzelli S., Di Trani L., Fabiani C., **Campitelli L.**, De Marco M.A., Aguilera J.F., Zambon M., Donatelli I. (2005) Serological analysis of humans exposed to avian H7 influenza viruses in Italy between 1999 and 2003. *J. Infect. Dis.* 192(8):1318_22.
- 41) Puzelli S., Di Trani L., Fabiani C., **Campitelli L.**, De Marco M.A., Aguilera J.F., Zambon M., Donatelli I. (2006) Reply to Skowronski et al. Human Illness and Isolation of Low Pathogenicity Avian Influenza Virus of the H7N3 Subtype in British Columbia, Canada. *J. Infect. Dis.* 193:900_01
- 42) De Marco M.A., Foni E., **Campitelli L.**, Delogu M., Raffini E., Chiapponi C., Barigazzi G., Cordioli P., Di Trani L., Donatelli I. (2005) Influenza virus circulation in wild aquatic birds in Italy during H5N2 and H7N1 poultry epidemic periods (1998 to 2000). *Avian Pathol.* 34(6):480_5.
- 43) Giannecchini S., **Campitelli L.**, Calzoletti L., De Marco M.A., Azzi A., Donatelli I. (2006) Comparison of in vitro replication features of H7N3 influenza viruses from wild ducks and turkeys: potential implications for interspecies transmission. *J. Gen. Virol.* 87(Pt 1):171_5.
- 44) Del Porto F., Laganà B., Biselli R., Donatelli I., **Campitelli L.**, Nisini R., Cardelli P., Rossi F., D'Amelio R. (2006) Influenza vaccine administration in patients with systemic lupus erythematosus and rheumatoid arthritis. Safety and immunogenicity. *Vaccine.* 24(16):3217_23.
- 45) **Campitelli L.**, Ciccozzi M., Salemi M., Taglia F., Boros S., Donatelli I., Rezza G. (2006) H5N1 influenza virus evolution: a comparison of different epidemics in birds and humans (1997_2004). *J. Gen. Virol.* 87:955_60.
- 46) Di Trani L., Bedini B., Donatelli I., **Campitelli L.**, Chiappini B., De Marco M.A., Delogu M., Buonavoglia C., Vaccari G. (2006) A sensitive one_step real_time PCR for detection of avian influenza viruses using a MGB probe and an internal positive control. *BMC Infect. Dis.* 6:87.
- 47) **Campitelli L.** and Donatelli I. (2006) WHO coordination of influenza global plan for possible avian influenza pandemic: Progress, Status and lessons to be learned. In *Recent Developments on the Avian Influenza (H5N1) crisis*. Edited by J.P. Wong. Transworld Research Network.
- 48) Ciccozzi M., **Campitelli L.**, Rezza G. Influenza aviaria: epidemiologia ed evoluzione di H5N1. *Notiziario dell'Istituto Superiore di Sanità*, Luglio_Agosto 2006, Vol. 19, n.7_8.
- 49) **Campitelli L.**, Facchini M., Di Martino A., Spagnolo D., Calzoletti L., Fabiani C., Bedini B., Grisetti T., Di Trani L., Donatelli I. Indagini virologiche e siero-epidemiologiche su virus influenzali aviari e sviluppo di un vaccino pandemico. Progetto europeo FLUPAN "Preparing for an influenza pandemic". Rapporto preliminare. Rapporti Istisan 06/22, 2006.
- 50) Delogu M., **Campitelli L.**, Di Trani L., Donatelli I. Ruolo dell'avifauna selvatica nell'ecologia dell'influenza: 14 anni di studio longitudinale in Italia. *Notiziario dell'Istituto Superiore di Sanità*, Luglio_Agosto 2006, Vol. 19, n.7_8.
- 51) **Campitelli L.**, Beneduce F., Calzoletti L., Donatelli I. Il vaccino pandemico: problemi e nuove strategie di produzione. *Notiziario dell'Istituto Superiore di Sanità*, Luglio_Agosto 2006, Vol. 19, n.7_8.
- 52) Ciccozzi M., Montieri S., Facchini M., Rezza G., Donatelli I., **Campitelli L.** (2007) Evolutionary analysis of HA and NS1 genes of H5N1 influenza viruses in 2004_2005 epidemics. *Avian Dis.* 51(s1):455_60 (accettato a Giugno 2006).
- 53) Di Trani L., Savarino A., **Campitelli L.**, Norelli S., Puzelli S., D'Ostilio D., Vignolo E., Donatelli I., Cassone A. Different pH requirements are associated with divergent inhibitory effects of chloroquine on human and avian influenza A viruses. *Virol. J.* 2007 May 3;4:39.
- 54) Duan L., **Campitelli L.**, Fan XH, Leung YH, Vijaykrishna D, Zhang JX, Donatelli I., Delogu M., Li KS, Foni E, Chiapponi C, Wu WL, Kai H, Webster RG, Shortridge KF, Peiris JS, Smith GJ, Chen H, Guan Y. Characterization of low pathogenic H5 subtype influenza viruses from Eurasia: implications for the origin of highly pathogenic H5N1 viruses. *J. Virol.* 2007 Jul;81(14):7529_39.
- 55) de Jong JC, Smith DJ, Lapedes AS, Donatelli I., **Campitelli L.**, Barigazzi G, Van Reeth K, Jones TC, Rimmelzwaan GF, Osterhaus AD, Fouchier RA. Antigenic and genetic evolution of swine influenza A (H3N2) viruses in Europe. *J. Virol.* 2007 Apr;81(8):4315_22.
- 56) Giannecchini S., **Campitelli L.**, Bandini G., Donatelli I., Azzi A. Characterization of human H1N1 influenza virus variants selected in vitro with zanamivir in the presence of sialic acid-containing molecules. *Virus Res.* 2007 Nov;129(2):241_5.
- 57) A. Whiteley, D. Major, I. Legastellois, **L. Campitelli**, I. Donatelli, C.I. Thompson, M.C. Zambon, J.M. Wood and W.S. Barclay. 2007. Generation of candidate human influenza vaccine strains in cell culture_ rehearsing the European response to an H7N1 pandemic threat. *Influenza and other respiratory diseases.* 1:157_166
- 58) **Campitelli L.**, Di Martino A., Spagnolo D., Smith GJ, Di Trani L., Facchini M., De Marco M.A., Foni E, Chiapponi C, Martin AM, Chen H, Guan Y, Delogu M, Donatelli I. (2008) Molecular analysis of avian H7 influenza viruses circulating in Eurasia in 1999_2005: detection of multiple reassortant virus genotypes. *J. Gen. Virol.* 89:48_59.
- 59) Babakir_Mina M, Ciccozzi M, **Campitelli L.**, Aquaro S, Lo Coco A, Perno CF, Ciotti M. (2009) Identification of the novel KI Polyomavirus in paranasal and lung tissues. *J. Med. Virol.* 81(3):558_61.
- 60) Cox RJ, Pedersen G, Madhun AS, Svindland S, Sævik M, Breakwell L, Hoschler K, Willemsen M, **Campitelli L.**, Nøstbakken JK, Weverling GJ, Klap J, McCullough KC, Zambon M, Kompier R, Sijns H. (2011) Evaluation of a virosomal H5N1 vaccine formulated with Matrix M™ adjuvant in a phase I clinical trial. *Vaccine.* 19;29(45):8049_59. Cox RJ, Major D, Pedersen G, Pathirana RD, Hoschler K, Guilfoyle K, Roseby S, Bredholt G, Breakwell L, Sijns H. (2015) Matrix M□ H5N1 vaccine induces cross reactive H5N1 humoral immune responses and provides protection

from highly pathogenic influenza challenge in ferrets. PLoS One. 10(7):e0131652.

Technical publications

- 1) EU Vaccine Batch Release Annual Report – Anno 1997
- 2) EU Vaccine Batch Release Annual Report – Anno 1998
- 3) EU Vaccine Batch Release Annual Report – Anno 1999
- 4) EU Vaccine Batch Release Annual Report – Anno 2000
- 5) EU Vaccine Batch Release Annual Report – Anno 2001
- 6) EU Vaccine Batch Release Annual Report – Anno 2002
- 7) EU batch release procedure – Viral vaccines _ Annual report 2003 Rapporti ISTISAN Interni 04/1
- 8) EU batch release procedure – Viral vaccines _ Annual report 2004. Rapporti ISTISAN Interni 05/3
- 9) EU batch release procedure – Viral vaccines _ Annual report 2005. Rapporti ISTISAN Interni 06/1
- 10) EU batch release procedure – Viral vaccines _ Annual report 2006. Rapporti ISTISAN Interni 07/1
- 11) EU batch release procedure – Viral vaccines _ Annual report 2007. Rapporti ISTISAN Interni 08/1
- 12) EU batch release procedure – Viral vaccines _ Annual report 2008. Rapporti ISTISAN Interni 09/2
- 13) EU batch release procedure – Human vaccines _ Annual report 2009. Rapporti ISTISAN Interni 10/1
- 14) EU batch release procedure – Human vaccines _ Annual report 2010. Rapporti ISTISAN Interni 11/2
- 15) EU batch release procedure – Human vaccines _ Annual report 2011. Rapporti ISTISAN Interni 12/1
- EU batch release procedure – Human vaccines _ Annual report 2012. Rapporti ISTISAN Interni 13/1

16) EU batch release procedure – Human vaccines _ Annual report 2013 _ Rapporti ISTISAN Interni 14/2 17) EU batch release procedure – Human vaccines _ Annual report 2014 _ Rapporti ISTISAN Interni 15/2 18) EU batch release procedure – Human vaccines _ Annual report 2015 _ Rapporti ISTISAN Interni 16/1

Projects

_ Several Italian research projects on influenza viruses circulating in non_human species _ EC project FLUPAN "Preparing for an influenza pandemic" – V EU research framework programme _ EC project PANFLUVAC "Efficacious vaccine formulation system for prophylactic control of influenza" – VI EU research framework programme _ Twinning project Italy_Turkey "Quality Control Tests for Human Vaccines and Sera". _ IMI2 project VAC2VAC "Vaccine batch to vaccine batch comparison by consistency testing" n. 2014_02136 (currently ongoing)

Memberships

Expert of the Group 15 of European Pharmacopeia (Human vaccines) Expert of the OCABR Drafting Group for vaccines, of EDQM. Member of the mRNAC working party of the European Pharmacopeia

Other Relevant Information