

Curriculum Vitae

Personal information **Maurizio Massella**

Work experience

From December 1998

To October 2017

RESEARCHER- Istituto Superiore Sanità-(ISS)- Italy

Activities: Clinical Trial on HIV infection

From October 2017

To date

Pharmacists- Agenzia Italiana del Farmaco (AIFA)- Italy

Activities: Clinical Trials Scientific Assessor (Regulatory/Clinical) at the Clinical Trials Office, supporting the Head of the Clinical Trials Office in the management of all scientific and regulatory activities related to Clinical Trials assessment and authorization. Tutoring of new assessors

Education and training

Degree on Pharmacy 25/07/1995

University of Perugia_Italy

Master II level in PharmacoEconomy

University of Milano- Italy

Specialty Training Courses:

Basic epidemiology-ISS-2000

Advanced epidemiology-ISS-2000

Pharmaco-epidemiology-ISS-2001

Basic statistic-ISS-2001

Advanced Statistic-ISS-2002

Additional information

Publications

- 1) **Regulatory Considerations on the use of Machine Learning based tools in Clinical Trials** Maurizio Massella, Diego Alejandro Dri, Donatella Gramaglia. Health Technol 2022;12(6):1085_1096. doi: 10.1007/s12553_022_00708_0
- 2) **Clinical Trials and Machine Learning: Regulatory Approach Review** Dri DA, Massella M, Gramaglia D, Marianecci C, Petraglia S. Rev Recent Clin Trials . Volume 16 , Issue 4 , 2021 Published on: 15 July, 2021 Page: [341 – 350]
- 3) <https://www.aifa.gov.it/> **Guide to the submission of a request for authorisation of a Clinical Trial involving the use of Artificial Intelligence (AI) or Machine Learning (ML) system** Aifa working group: D. Gramaglia, D. A. Dri, M. Massella, N.M. Verrelli, G. Praticò, S. Petraglia, P. Foggi, M. Di Marzo, E. Agricola
- 4) Massella M, Ivanovic J, Bellagamba R, De Vita R, Fracasso L, Tozzi V, Fragola V, Rizzica M, Narciso P. **Cost of surgical intervention for reconstructive therapy of HIV-associated facial lipoatrophy**. Patient Prefer Adherence. 2011;5:223_8.
- 5) Massella M, Bucciardini R, Fragola V **"Qualità della Vita" del paziente: Outcome per una migliore valutazione di strategie terapeutiche**. Notiziario ISS 2006, Volume 19, Numero 4
- 6) Rezza G, Scalia Tomba G, Martucci P, Massella M, Noto R, De Risio A, Brunetti B, Ardita S, Massella M., Starnini G **Prevalence of the use of old and new drugs among new entrants in Italian prisons**. Ann Ist Super Sanita. 2005;41(2):239_45
- 7) Bucciardini R, Massella M, Corpolongo A, Narciso P, Fragola V, Mirra M, Donnini S, Viganò O, Costarelli S, Tozzi V

T20QOL: an observational multicenter cohort study to evaluate the quality of life in HIV patients treated with enfuvirtide (ENF, T_20) in combination with an optimized background therapy. *Biologics: Targets & Therapy* 2008;2(3) 1_5.

8) **Population pharmacokinetics and pharmacogenetics of ritonavir boosted darunavir in the presence of raltegravir or tenofovir disoproxil fumarate/emtricitabine in HIV infected adults and the relationship with virological response: a sub_study of the NEAT001/ANRS143 randomized trial.** Dickinson L, Gurjar R, Stöhr W, Bonora S, Owen A, D'Avolio A, Cursley A, Molina JM, Fäetkenheuer G, Vandekerckhove L, Di Perri G, Pozniak A, Richert L, Raffi F, Boffito M; NEAT001/ANRS143 Study Group. *J Antimicrob Chemother.* 2020 Mar 1;75(3):628_639. doi: 10.1093/jac/dkz479

9) **Antiretroviral resistance at virological failure in the NEAT 001/ANRS 143 trial: raltegravir plus darunavir/ritonavir or tenofovir/emtricitabine plus darunavir/ritonavir as first_line ART.** Lambert_Niclot S, George EC, Pozniak A, White E, Schwimmer C, Jessen H, Johnson M, Dunn D, Perno CF, Clotet B, Plettenberg A, Blaxhult A, Palmisano L, Wittkop L, Calvez V, Marcelin AG, Raffi F; NEAT 001/ANRS 143 Study Group. *J Antimicrob Chemother.* 2016 Apr;71(4)

10) Massella M, Arcieri R. **Dall' AZT all' HAART Positifs_Infezioni da HIV:** Repertorio delle sperimentazioni teapautiche Edizione 2003 Anno 9

11) **Host and disease factors are associated with cognitive function in European HIV infected adults prior to initiation of antiretroviral therapy.** Winston A, Stöhr W, Antinori A, Arenas_Pinto A, Llibre JM, Amieva H, Cabié A, Williams I, Di Perri G, Tellez MJ, Rockstroh J, Babiker A, Pozniak A, Raffi F, Richert L; NEAT 001/Agence Nationale de Recherche sur le SIDA (ANRS) 143 Study Group. *HIV Med.* 2016 Jun;17(6):471_8.

12) **Bone mineral density and inflammatory and bone biomarkers after darunavir_ritonavir combined with either raltegravir or tenofovir_emtricitabine in antiretroviral_naive adults with HIV_1: a substudy of the NEAT001/ANRS143 randomised trial.** Bernardino JJ, Mocroft A, Mallon PW, Wallet C, Gerstoft J, Russell C, Reiss P, Katlama C, De Wit S, Richert L, Babiker A, Buño A, Castagna A, Girard PM, Chene G, Raffi F, Arribas JR; NEAT001/ANRS143 Study Group. *Lancet HIV.* 2015 Nov;2(11)

13) Narciso P, Bucciardini R, Tozzi V, Bellagamba R, Ivanovic J, Giulianelli M, Scevola S, Palummieri A, Fragola V, Massella M, Fracasso L, De Vita R, Pierro P, Del Maestro A, Mirra M, Weimer L. **Immediate versus delayed surgical intervention for reconstructive therapy of HIV_associated facial lipoatrophy: a randomized openlabel study** *AIDS Res Hum Retroviruses*

14) L. Kondili, MG Quaranta, L.Falzano, A. Mallano, M.Mirra, LE Weimer, L.Fucili, M. Di Gregorio, S. Lucattini, M. Massella, R. Terlizzi, E. Olivieri, F. Magnani, A. Mattei, S. Rosato, ME Tosti, S. Vella and PITER Collaborating group **PITER_HCV cohort study as a part of the italian platform for the study of viral hepatitis therapies** *Rapporti ISTISAN* 15/35

15) Lambert_Niclot S, George EC, Pozniak A, White E, Schwimmer C, Jessen H, Johnson M, Dunn D, Perno CF, Clotet B, Plettenberg A, Blaxhult A, Palmisano L, Wittkop L, Calvez V, Marcelin AG, Raffi F; NEAT 001/ANRS 143 **Study Group. Antiretroviral resistance at virological failure in the NEAT 001/ANRS 143 trial: raltegravir plus darunavir/ritonavir or tenofovir/emtricitabine plus darunavir/ritonavir as first_line ART.** *J Antimicrob Chemother.* 2015 Dec 24.

16) Raffi F, Babiker AG, Richert L, Molina JM, George EC, Antinori A, Arribas JR, Grarup J, Hudson F, Schwimmer C, Saillard J, Wallet C, Jansson PO, Allavena C, Van Leeuwen R, Delfraissy JF, Vella S, Chêne G, Pozniak A; NEAT001/ANRS143 Study Group. **Ritonavir_boosted darunavir combined with raltegravir or tenofovir-emtricitabine in antiretroviral_naive adults infected with HIV_1: 96 week results from the NEAT001/ANRS143 randomised non_inferiority trial** *Lancet.* 2014 Nov 29;384(9958):1942_51

17) Winston A, Stöhr W, Antinori A, Arenas_Pinto A, Llibre JM, Amieva H, Cabié A, Williams I, Di Perri G, Tellez MJ, Rockstroh J, Babiker A, Pozniak A, Raffi F, Richert L **Host and disease factors are associated with cognitive function in European HIV infected adults prior to initiation of antiretroviral therapy.** ; NEAT 001/ANRS 143 Study Group *HIV Med.* 2015 Nov 26.

18) **Sustained increase of serum creatine phosphokinase levels and progressive muscle abnormalities associated with raltegravir use during 32_week follow_up in an HIV_1 experienced patient on simplified HAART regimen, intolerant to protease inhibitors and abacavir: a case report .** Cirioni O, Weimer LE, Fragola V, Giacometti A, Gabrielli E, Marchionni E, Massella M, Barchiesi F. *West Indian Med J.* 2013;62(4):377_9.

19) Weimer LE, Fragola V, Floridia M, Guaraldi G, Ladisa N, Francisci D, Bellagamba R, Degli Antoni A, Parruti G, Giacometti A, Manconi PE, Vivarelli A, D'Ettorre G, Mura MS, Cicalini S, Preziosi R, Sighinolfi L, Verucchi G, Libertone R, Tavio M, Sarmati L, Bucciardini R; ISS_NIA Study Group. **Response to raltegravir_based salvage therapy in HIV_infected patients with hepatitis C virus or hepatitis B virus coinfection** *J Antimicrob Chemother.* 2013 Jan;68(1):193_9.

20) Bucciardini R, D'Ettorre G, Baroncelli S, Ceccarelli G, Parruti G, Weimer LE, Fragola V, Galluzzo CM, Pirillo MF, Lucattini S, Bellagamba R, Francisci D, Ladisa N, Degli Antoni A, Guaraldi G, Manconi PE, Vullo V, Preziosi R, Cirioni O, Verucchi G, Floridia M; ISS_NIA study group. **Virological failure at one year in triple_class experienced patients switching to raltegravir_based regimens is not predicted by baseline factors.** *Int J STD AIDS.* 2012 Jul;23(7):459_63

21) Narciso P, Bucciardini R, Tozzi V, Bellagamba R, Ivanovic J, Giulianelli M, Scevola S, Palummieri A, Fragola V, Massella M, Fracasso L, De Vita R, Pierro P, Del Maestro A, Mirra M, Weimer L. **Immediate versus delayed surgical intervention for reconstructive therapy of HIV_associated facial lipoatrophy: a randomized open_label study** *AIDS Res Hum Retroviruses.*

22) Bucciardini R. Massella M, Corpolongo A, Narciso P, Fragola V, Mirra M, Donnini S, Viganò O, Costarelli S, Tozzi V **T20QOL: an observational multicenter cohort study to evaluate the quality of life in HIV patients treated with enfuvirtide (ENF, T_20) in combination with an optimized background therapy.** *Biologics: Targets & Therapy* 2008;2(3) 1_5

23) Bucciardini R, Fragola V, Massella M, Polizzi C, Mirra M, Goodall R, Carey D, Hudson F, Zajdenverg R, Floridia M; **Initio Trial International Coordinating Committee. Health_related quality of life outcomes in HIV_infected patients starting different combination regimens in a randomized multinational trial: the INITIO_QoL substudy.** *AIDS Res Hum Retroviruses.* 2007 Oct;23(10):1215_22.

24) Bucciardini R, Murri R, Guarinieri M, Starace F, Martini M, Vatrella A, Cafaro L, Fantoni M, Grisetti R, Monforte A, Fragola V, Arcieri R, Del Borgo C, Tramatin A, Massella M, Lorenzetti D, Vella S. **ISSQoL: a new questionnaire for evaluating the quality of life of people living with HIV in the HAART era.** *Qual Life Res.* 2006 Apr;15(3):377_90.

25) Floridia M, Giuliano M, Germinario EAP, Massella M, Binelli A, Amici R. **Gli antiretrovirali in gravidanza. Giornale Italiano delle Malattie Infettive** Volume 7 Supplemento n. 2_ 2001

26) Bucciardini R, Wu A. W, Floridia M, Fragola V, Ricciardulli D, Tomino C, Weimer L.E, Pirillo M. F, Mirra M, Marzi M, Giannini G, Galluzzo C. M, Andreotti M, Massella M and Vella S. **Quality of life in a randomised clinical trial of zidovudine plus didanosine plus nevirapine or zidovudine plus didanosine for antiretroviral_naive**

patients with a clinical diagnosis of AIDS or CD4 counts below 200/mm3 (study ISS 047). AIDS. 2000 volume 14: 2567_2574

27) **Hospitalizations and costs of treatment for protease inhibitor _based regimens in patients with very advanced HIV_infection (CD4 < 50/mm(3)).** Floridia M, Massella M, Bucciardini R, Perucci CA, Rossi L, Tomino C, Fragola V, Ricciardulli D, Galluzzo CM, Giannini G, Pirillo MF, Andreotti M, Mirra M, Vella S. HIV Clin Trials. 2000 Sep_Oct;1(2):9_16

28) **The role of patient reported outcomes in the regulatory process needs to be better defined PROMote group,** Rome, Italy BMJ 4 February 2009 29) Enciclopedia Medica Italiana III Aggiornamento dell Seconda edizione: Inibitori dell'Entrata dell'HIV 30) A factor analytic study of the Italian National Institute of Health Quality of Life _ Core Evaluation Form (ISSQoL_CEF). Lauriola M, Murri R, Massella M, Mirra M, Donnini S, Fragola V, Ivanovic J, Pavoni M, Mancini G, Bucciardini R. Patient Prefer Adherence. 2010 Mar 24;4:33_44.

Projects

INITIO Trial
SIMBA Trial
NEAT 001/ANRS 143

Memberships

Other Relevant Information

Expertise:

Regulatory
Clinical Research
Machine Learning
Decentralized Clinical Trial