Curriculum Vitae

Name and Surname Franco Di Cesare

Professional /Educational Qualifications

Year(s)	*Qualification*	*Institution*
1987	Medical Doctor	School of Medicine, University of Rome "Sapienza", Rome, Italy
1993	European Board-Certified Clinical Psychology	School of Medicine, University of Rome "Sapienza", Rome, Italy
2008-2011	Professor of theories and methods of behavioral and personality assessment	School of Medicine, University of Rome "Sapienza", Rome. Italy Department of Psychiatric Sciences and Psychological Medicine
2010	Assistant Professor of Health Psychology	John Cabot University (USA-Italy)
2023	Professor of Pharmacology	Unicamillus University, Rome, Italy

Memberships of Learned Societies, Associations

- Current Member of the International Society of CNS Clinical Trials & Methodology (ISCTM)
- Former member of the "International Psychogeriatrics Association"
- Former member of the "Movement Disorder Society"
- Medical License n.2099 issued by "Ordine Provinciale dei Medici Chirurghi ed Odontoiatri, L'Aquila" on the 22th December 1987

Languages – Spoken/Read/Translation capabilities/qualifications

Italian	Fluent
English	Fluent

Professional Experience

Current — **Pharmaceutical Physician** - Independent Consulting Services for Neuroscience and CNS Therapeutics Development (Rome, Italy)

Oct 2017-Aug 2023 — **Co-Founder, Co-owner and Director**
Leoben Research srl (Rome, Italy)

Leoben Research (LBR) is a provider of medical and scientific services for mental healthcare and clinical research industries.

Jan-March2023: *Consulting for a Biotech on Regulatory Strategy and Clinical Development Plan for an undisclosed drug treatment for Refractory Major Depressive Disorder.*

Nov2021 March 2023: *Medical Consultancy role at Residenze di Esper (Fiuggi, FR, Italy), organisation design and mental healthcare delivery for a 30-bed Residential 24-h Psychiatric Rehabilitative Community*

Apr-Sept 2022*: Psychiatrist (consultancy) at Villa Giuseppina (S.Giuseppe S.p.A.) in Rome, organisation design and mental healthcare delivery for a 40-bed Residential 24-h Psychiatric Rehabilitative Community*

Mar-Sept 2021: *Medical Director (full time consultancy), Psychiatry Covid-19 Emergency, ASL Rieti, Italian National Health System*

2018-2023: *LBR has been also developing of proprietary innovative clinical assessment methods for applications in clinical research and healthcare for under-resourced healthcare systems:* Zambia Paediatric Cognitive Assessment Tools Program to evaluate cognitive impairment in a paediatric population in Sub-Saharan countries

2010-2018 **Co-Founder, Co-owner and Director**
Leoben Research ltd (Glasgow, UK)

Leoben Research was a medical knowledge company providing medical and scientific services to the bio-pharmaceutical industry.

Dec2017-Nov2018: *Medical Lead for Naldemedine, GI-Pain Therapeutic Area , European Medical Affairs at Shionogi, London, UK.*

Jun2016-Oct2017: *Chief Medical Officer, Neurocentrix, Edinburgh, UK*

Medical Lead for Clinical Program Design and Early Phase Development of a new formulation of low-dose Ketamine for the treatment of suicidality.

Protocol development and set-up of the study "A Randomised, Double Blind, Placebo Controlled, Parallel Group, Dose-Response, Add-on, Phase 2, Multicentre Study to Evaluate NX-2001 for the Treatment of Suicidal Ideation to Prevent Suicidal Behaviour in Patients Receiving Standard of Care (SOC) Treatment for Suicide Risk Management".

Design and development of a Quality Risk Management System for Ketamine drug development.

Sep2014-Apr2015: *Medical Expert, Clintec (an International CRO) for Britannia Pharmaceuticals/Stada Group*

Clinical development strategy and protocol design to evaluate a new titration scheme of Apomorphine Injectable formulation in advanced Parkinson's Disease.

Jul2011-Sep2014: *Global Medical Lead at Pfizer/Neusentis (Cambridge, UK)*

As being part of a cross-functional matrix organisation, the aim of the medical lead role was to provide medical expertise across the different functional groups involved in the delivery of global drug development programs. Essential elements of the role and primary responsibilities: to provide medical expertise to the clinical development strategy, protocol design and development, product safety management risk, Investigator's Brochure, clinical study reporting and data publication; trial medical monitoring and safety assessment. The Medical Lead provided medical expertise to support in-house or outsourced activities relating to formulation development, preclinical safety & toxicology, genetics, clinical operations, clinical pharmacology, clinical quality assurance, brain imaging, drug safety, biostatistics, and regulatory affairs. The Medical Lead was a member of the team assigned to set a network of leading scientific institutions in the EU and USA to foster innovation in pain therapies.

Medical Lead for the Early Phase Clinical development assigned to the pain and regenerative medicine programs and clinical studies:

- PF-03049423, a PDE5 inhibitor, in acute ischemic stroke;
- Nav.1.8, Nav.1.7, and PanTrk-modulators in acute and chronic pain (compounds PF-05089771, PF-06305591, and PF-04531083)
- *Kv.7 in Epilepsy (PF-05895162)*

Details on the PF-03049423, a PDE5 inhibitor, in acute ischemic stroke study can be found at https://clinicaltrials.gov/ct2/show/NCT01208233.

Phase 2a Studies

- Evaluation Of The Efficacy And Safety Of Single Doses Of PF-05089771 In Patients With Primary (Inherited) Erythromelalgia (IEM)
- A Safety And Tolerability Study Of PF-05089771 In Healthy Subjects And In Subjects With Osteoarthritis Of The Knee
- Efficacy Of PF-05089771 In Treating Postoperative Dental Pain
- A Clinical Trial To Evaluate PF-05089771 On Its Own And As An Add-On Therapy To Pregabalin (Lyrica) For The Treatment Of Pain Due To Diabetic Peripheral Neuropathy (DPN)
- Efficacy Of PF-04531083 In Treating Post-Surgical Dental Pain
- Study Evaluating The Safety And Efficacy Of PF-03049423 In Subjects With Ischemic Stroke

Phase 1 Studies

- A Single Dose Escalation Study In Healthy Volunteers To Determine The Pharmacokinetics, Safety And Tolerability Of PF-05089771 In Healthy Volunteers
- The Safety and Tolerability of PF-05089771 Investigated in Healthy Subjects Over a 14 Day Dosing Period.
- Safety And Tolerability Study Of BID Titration Scheme With PF-05089771
- A Study Comparing PF-05089771 TS Tablet to PF-05089771 TS Oral Dispersion In The Fasted State And To PF-05089771 TS Tablet In The Fasted And Fed State
- A Study Comparing PF-05089771 TS Capsule To PF-05089771 TS Oral Dispersion In The Fasted State
- Relative Bioavailability With PF-05089771 Capsule Versus Oral Dispersion
- Drug-Drug Interaction Study With PF-05089771
- Safety and Tolerability Study of Multiple Doses of PF-06305591
- Study to Investigate the Safety, Tolerability, Pharmacokinetics of PF-06305591 in Healthy Male and Female Subjects

- A Study In Healthy People To Evaluate Safety, Toleration And Time Course Of Plasma Concentration Of Multiple Oral Doses Of PF-04895162
- A Study to Evaluate Safety, Toleration and Time Course of Plasma Concentration of Multiple Oral Doses of PF-06273340 in Healthy Subjects of Two Age Groups, Aged 18-55 Years (Group 1) and Aged 56-75 Years (Group 2)
- Effect Of PF-06305591 On Capsaicin And Capsaicin/Heat-Induced Neurogenic Flare
- Cold Pressor Test to Assess the Effect of PF-06305591 on Pain Intensity Evoked by Cold in Healthy Male Subjects

2010: *BMS-820836 in Major Depressive Disorder (Study CN-161-007). Raters Training and Qualification.*
"A Multicenter, Randomized, Double-Blind, Active Controlled, Comparative, Fixed-Dose, Dose Response Study of the Efficacy and Safety of BMS-820836 in Patients With Treatment Resistant Major Depression (TRD)." *Medical Expert and Trainer on administration of Montgomery-Asberg Depression Rating Scale (MADRS), Hamilton Depression Rating Scale (HDRS), and Neuropsychiatric Interview MINI.*

Dec2007-May2010 **Medical Director, CNS, Medical & Scientific Affairs**
i3 Ingenix Pharmaceutical Services *(Rome, Italy)*

i3 (now Syneos Health), a leading global pharmaceutical services company that provides integrated strategies and solutions throughout the drug product life-cycle.

- The Medical Director provides medical and scientific perspectives into the design of clinical development programs and study protocols; provides expert input into the development and review of clinical documents.
- Is responsible for providing professional medical and clinical services for clinical trials with a concentration on provision of medical monitoring and safety management for a project within a specific CNS therapeutic area.
- Other areas of interested and activity: biomarkers applied to clinical CNS drug development and trial design.

Sept2004-Nov2007 **Co-founder & Managing Director**
Exgenis Ltd *(Glasgow, UK)*

Exgenis, a UK-based medical technology and drug development organisation with staff of 32 people based in UK, Italy, Germany, Russia, Ukraine, and Australia.

As contract research organisation, Exgenis delivered regulatory phase 2 clinical Proof-of Concept (POC) studies in the following therapeutic indications:

- Melatonin Controlled Release in Sleep and Circadian Rhythm Disorders,
- Rambazole in Severe Plaque Psoriasis,
- Misoprostol in Labour Induction.

Selected trial experience:

- A double-blind placebo controlled cross-over study to determine if 1.5 and 3mg of APL510 can normalise sleep patterns in elderly subjects with difficulty in maintenance of sleep and/or initiating sleep onset.
- A double-blind placebo-controlled cross-over study to determine if melatonin can improve the length of day-time sleep in subjects with transient misalignment of the sleep-wake cycle as a result of working permanent night shifts.

Apr2003-Sept2004

Managing Director and Director for Medical & Scientific Affairs

Medicinal Development Pharma (*Milan, Italy****)***

Medicinal Development Pharma (MeDePha), an international full-service clinical research organisation providing Medical-Scientific, Regulatory, Clinical Operations, Data Management & Biostatistics, and Quality Assurance Services with staff of 27 people based in Italy and the UK.

As Director for Medical & Scientific Affairs, I delivered scientific consulting on clinical program design and protocol development Phase 2 Proof-of-Concept studies for Pharmaceuticals & Biotech companies in the following neurological indications:

- Neuropathic Pain,
- Fibromyalgia,
- Sleep Disorders,
- Alzheimer's Disease and Mild Cognitive Impairment,
- Post-Stroke cognitive recovery.

Design and implementation of a Rater's training and qualification program for an international phase 2B study on Safinamide to treat Parkinson's Disease (Newron Pharmaceuticals).

Apr2001-Apr2003

Global Director, Medical Affairs

Ingenix Pharmaceutical Services *(London, UK)*

Ingenix Pharmaceutical Services was a leading global pharmaceutical services company that provides integrated strategies and solutions throughout the drug product life-cycle.

- Medical Affairs function at Ingenix Pharmaceutical Services was ultimately responsible for providing medical monitoring and safety assessment and reporting services.
- I was responsible for the management of functionally integrated 7 medical teams located in the US (Basking Ridge, NJ, Cary NC, San Diego

CA), Europe (Maidenhead UK; Rome, Italy; and Prague, Czech Republic) and Asia-Pacific (Hong-Kong). Seventy-four medical monitoring projects in different therapeutic areas/indications (Psychiatry, Neurology, Analgesia, Endocrinology, AIDS/Anti-Infectives, Oncology, Cardiovascular & other Internal medicine) and across all phases of drug development over my management period.

- As *Therapeutic Area (TA) Leader for CNS initiatives,* I was responsible for providing information of direct relevance for lead identification of new business opportunity with regards to a specific therapeutic area.
  Activities include both providing input for strategic business planning & development by monitoring R&D pipelines, Drugs under development, Drug approvals, Regulatory environment, etc. and communicating to other relevant Ingenix Executives and Business unit(s); and facilitating the creation and extending relationships with Sponsor medical & scientific representatives by attending scientific congresses and meetings, by personal business contacts.

Sept1999-Apr2001 ***International Director, Medical & Scientific Affairs***
Ingenix Pharmaceutical Services *(London, UK)*

Management of International Medical & Scientific Affairs groups in Europe (London & Paris). Twenty-eight is the number of completed/initiated medical projects over the period. They were across different therapeutic areas/indications: Psychiatry and Neurology, Analgesia, AIDS/Anti-Infectives, Cardiovascular & other Internal medicine indications) and across all phases of drug development.

Aug1998-Sept1999 **Director, Medical Affairs**
Ingenix Pharmaceutical Services - Worldwide Clinical Trials *(London, UK)*

Responsibilities included (but were not limited to) the management of Medical Team monitoring international clinical trials in neuropsychiatric indications:

- Schizophrenia and Suicidality (InterSePT)
- Major Depressive Disorder,
- Bipolar Disorders,
- Mild Cognitive Impairment,
- Alzheimer's disease.

Feb1996-Aug1998 **CNS Therapeutic Area, Supervisor**
Institute of Pharmacological Research, ACRAF S.p.A. *(Pomezia, Italy)*

ACRAF is a leading Italian pharmaceutical company.
I was responsible for CNS therapeutic area clinical development programs:

- AF-2968, an antidepressant agent,
- Eptastigmine, acetyl-cholinesterase inhibitor for *Alzheimer's disease*,
- Paracetamol in *Early Alzheimer's disease*.

Aug1995-Feb1996 **Pharmacoeconomics and Medical Services Department, Head**
Medical Research Division,
Wyeth-Lederle Italia S.P.A. *(Aprilia, Italy)*

Wyeth was a leading global pharmaceutical company.
My department provided scientific input for planning and designing studies for pharmaco-economic evaluation and post-marketing pharmaco-epidemiology.

Jan1994-Aug1995 **CNS Therapeutic Area Advisor**
Medical Research Division, Cyanamid Italia S.p.A - then renamed Wyeth-Lederle after merger with Wyeth-Ayerst in August 1994 (*Rome area, Italy)*

- Responsible for clinical program design and conduct of the early phase program in Europe on Thyreotropin-releasing-factor (TRH) extended release formulation in Neurodegenerative disorders (Alzheimer's Disease and Spino-cerebellar Ataxia).
- Regional Medical Monitor for phase III studies on Zaleplon in patients with primary *insomnia*.

May1992-Jan1994 **Quality and Safety Assurance, Supervisor**
Medical Research Division, Cyanamid Italia S.p.A *(Rome, Italy)*

- Pharmacovigilance and safety reporting to Regulatory Authorities.
- Clinical quality assurance and audit.

May1998-May1992 **Medical Advisor, CNS**
Medical Department, Poli Industria Chimica S.p.A *(Milan, Italy)*

Poli Industria Chimica was a leading Italian pharmaceutical company.

- Planning clinical development strategies.
- Supervising protocol design and clinical trial administration (*Dihydroergocristine for Cognitive Impairment and Dementia, Dihydroergocryptine for early Parkinson's disease; Quality of Life Outcome Research*).
- Scientific KOLs networking and liaison.

Dec1987-Dec1988 **Italian Army – Department of Applied Psychology**
Research on new clinical methods for personality assessment.
Monitoring of suicide risk in military service men.

March-Dec1987 **University of Rome "Sapienza"** (Rome, Italy)
Co-Investigator responsible for neuropsychological assessment in clinical trials (Idebenone in Alzheimer's disease; L-Acetil-Carnitine in Age-related Cognitive Impairment; Lisuride in Parkinson's Disease).

SUMMARY OF SPECIALISED THERAPEUTIC EXPERIENCE

Clinical program design, study protocol development, medical oversight and safety monitoring assessment of clinical trials, or medical scientific consulting:

- Mild Cognitive Impairment and Dementia (Alzheimer's Disease and Vascular)
- Parkinson's Disease
- Ischaemic Stroke
- Amyotrophic Lateral Sclerosis
- Pain and Analgesia (Diabetic Painful Neuropathy, Chemotherapy-induced Peripheral Neuropathy, Osteoarthritis, Dental Pain, Erythromyalgia), and Fibromyalgia (adult and juvenile)
- Opioid-induced Constipation
- Epilepsy
- Multiple Sclerosis
- Premenstrual Disorder
- Attention Deficit Hyperactivity Disorders (AD/HD)
- Major Depressive Disorder (adolescents, adults, elderly)
- Suicide Ideation and Behaviour
- Schizophrenia and schizoaffective disorders
- Bipolar Disorder
- Insomnia and Circadian Rhythm Disorder

Other research interests:

- Biologic and cognitive markers applied to CNS drug development.
- Paediatric cognitive assessment for under-resourced health care systems.
- Methods of behavioural assessment applied to neurotechnology development.

SELECTED PUBLICATIONS

Kemi Olugemo, Dragana Bugarski-Kirola, Gerard Dawson, Franco DiCesare, Dejan Stevanović; Janko Samardzic, Andreas Chatzittofis, Raenne Moore, Joris Verster, Lais Bhering, Eduard Vieta.
Conducting CNS trials during a public health emergency – lessons learned from the COVID-19 pandemic: a joint ISCTM/ECNP Working Group Consensus Paper. *Neuroscience Applied* 2, 2023, 101129, https://doi.org/10.1016/j.nsa.2023.101129.

Franco Di Cesare, Cristiana Di Carlo, Leonardo Di Cesare.
A New Pediatric Cognitive Assessment Tool to Advance Knowledge on Child's Cognitive Development, Health Risk Factors, and Health-Promoting Interventions in Sub-Saharan Regions. *Child Neuropsychology* (Submitted March 2023)

Franco Di Cesare, Cristiana Di Carlo, Giulia Piccinini, Leonardo Di Cesare.
WORDS: a new verbal memory test to evaluate cognitive health in a Zambian school-aged population. *Journal of Innovations in Clinical Neurosciences* 2023;20(7–9):11–17

Franco Di Cesare, Cristiana Di Carlo, Leonardo Di Cesare.
WAVES: a Novel Test to Evaluate Visuospatial Construction Ability in a School-aged *Journal of Innovations in Clinical Neurosciences* 2023;20(1-3):39-45

Franco Di Cesare, Cristiana Di Carlo, Leonardo Di Cesare.
Development of a Symbol Cancellation Test to evaluate attention in a school-aged Zambian population. *Journal of Innovations in Clinical Neurosciences* 2023; 20(1-3):46-52

Franco Di Cesare, Cristiana Di Carlo, Leonardo Di Cesare.
Development of a Cognitive Ability Assessment Tool (CAAT) for use in paediatric clinical trials in Sub-Saharan countries. *Journal of Innovations in Clinical Neurosciences* 2021;18(10–12):30–37

C. O'Gorman, R. Khoury, A. Anderson, M. Carter, F. Di Cesare, W. Chen, S. Dubé, L. Ereshefsky, T. Farchione, G. Grossberg, N. Hefting, S. Khan, S. Lind, V. Mantua, H. Moebius, T. Shiovitz, P. Rosenberg.
"A Framework for Developing Pharmacotherapy for Agitation in Alzheimer's Disease: Recommendations of the ISCTM Working Group." The Journal of Prevention of Alzheimer's Disease Published on-line June, 26, 2020 *J Prev Alzheimers Dis* (2020). https://doi.org/10.14283/jpad.2020.37

P. Chapel, L. Alphs, F.Di Cesare, S. Marder, M. Stewart et al.
"Assessment of Suicidal Ideation and Behavior: Report of the International Society for CNS Clinical Trials and Methodology Consensus Meeting." J Clin Psychiatry 2017;78(6):e638−e647

F. Di Cesare, J. Mancuso, B. Silver, P. Loudon.
"Assessment of cognitive and neurologic recovery in ischemic stroke drug trials. Results from a randomised, double-blind, placebo-controlled study." Journal of Innovations in Clinical Neurosciences, Innov Clin Neurosci 13 (9-10), 32-43. 2016 Oct 01.

F. Di Cesare, J. Mancuso, P. Woodward, M. Bednar, P. Loudon, for the A9541004 Stroke Study Group.

PDE5 inhibitor PF-03049423 Effect on Stroke Recovery. A Double-Blind, Placebo-Controlled Randomized Clinical Trial. Journal of Stroke and Cerebrovascular Diseases. November 2015, DOI: http://dx.doi.org./10.1016/i.jstrokecerebrovasdis.2015.11.026

F. Di Cesare, D. D'Ilario, M. Fioravanti.
"Differential characteristics of the aging process and the vascular cognitive impairment in the organization of memory retrieval." Journal of Neurocognitive Sciences. November 2012,15;322(1-2):148-51. Epub 2012 Aug 4.

F. Di Cesare, D. D'Ilario, M. Fioravanti.
"Memory as early marker of cognitive decline." European Journal of Neurology 16 (Suppl. 3), 439, 2009

F. Di Cesare, M. Novelli, C. Di Carlo, M. Fioravanti.
"A new computerized memory test to evaluate early cognitive decline and treatment response." European Journal of Neurology 16 (Suppl. 3), 450, 2009

M. Sagud, M. Jakovljievic, A. Mihalijevic-Peles, D. Tomic, F. Di Cesare.
"Agranulocytosis after addition of risperidone to clozapine treatment**"** Psychiatria danubina, 11 (3-4): 153-158, 1999

C. Landolfi, L. Soldo , L. Polenzani , C. Apicella , A. Capezzone de Joannon , L. Coletta , F. Di Cesare, F. Brufani, M. Pinza., C. Milanese.
"Inflammatory molecule release by beta-amyloid-treated T98G astrocytoma cells: role of prostaglandins and modulation by paracetamol." Eur. J. Pharmacol. 360(1): 55-64, 1998

M. Fioravanti, D. Agazzani, F. Di Cesare, A.E. Buckley.
"The aging of memory: a method for the assessment of qualitative changes". Arch. Gerontol. Geriatr. Suppl. 4, 75-84, 1994.

E. Malacco, F. Di Cesare.
"Effects of dihydroergocristine treatment on carbohydrate tolerance and cognitive function in patients with non-insulin-dependent diabetes". Current Therapeutic Research, 51, 4, 515-523, 1992.

M. Fioravanti, F. Di Cesare.
"Forgetting curves in long-term memory: evidence for a multistage model of retention". Brain and Cognition, 18, 116-124, 1992

M. Fioravanti, F. Di Cesare, B. Golfieri, D. D'Ilario, D. Agazzani.
II test di efficienza della memoria MET: un nuovo test per la valutazione clinica della memoria" (Memory Efficiency Test: a new test for clinical assessment of memory) Giornale di Neuropsicofarmacologia Clinica, 4, 125-130, 1992.

M. Fioravanti, F. Di Cesare.
"Memory improvement and pharmacological treatment: a method to distinguish direct effects on memory from secondary effects due to attention improvement". International Psychogeriatrics, 4, 199-126, 1992

F. Di Cesare, F. Mailland, G. Zavattini.
"Epidemiological study on the efficacy and safety of dihydroergocristine in impaired memory and behavioral functions in elderly"."Arzneimittel Forshung (Drug Research), 42 (ii), 1417-1421, 1992

R.W. Khulavy, L.C. Caterino, M. Fioravanti, F. Di Cesare, W.A. Stock.
"Measuring cognitive processes in patients with Parkinson's disease." Archives of Clinical Neuropsychology, 6, 319-325, 1991.

E. Catena, A. Bisetti, A. Ciaccia, F. Di Cesare, G. Zavattini, M. Fioravanti.
"Multicentre double-blind carboscysteine-sobrerol association vs. placebo: long-term study in patients with COLD" The European Respiratory Journal, 4, Suppl. 14, 529, 1991.

M. Fioravanti, F. Di Cesare, F. la Torre, A. Nicastro, S. Messinetti, R. Lazzari.
"Adattamento psicologico e riabilitazione ne paziente con enterostomia" In "Psicologia in ospedale: esperienze a confronto". (Psychological adjustment and rehabilitation in patient with enterostomy. In: Psychology at the Hospital – A comparison of experiences) G. Biondi (editor), Nuova Editrice Spada, Roma, 1991.

E. Catena, A. Bisetti, A. Ciaccia, F. Di Cesare, G. Zavattini, M. Fioravanti.
"L'associazione carbocisteina-sobrerolo e qualita' di vita in pazienti bronchitici cronici con severa ostruzione dell vie aeree." (Carbocysteine-sobrerol association and quality of life in patients with chronic bronchitis and severe airways obstruction). Medicina Toracica, 1, 53-57, 1990.

M. Fioravanti, F. Di Cesare, A Denaro, S. Bernarrdi, A, Buttinelli, C. Fieschi.
"Psychological adjustment to the disease and memory efficiency in Multiple Sclerosis: a prospective longitudinal investigation." In: A. Battaglia and G. Crimi (Eds): An update on Multiple Sclerosis. Monduzzi editore, Bologna, 1989.

M. Fioravanti, F. Di Cesare.
"Studio comparativo delle curve di acquisizione e di ritenzione tra parksoniani e pazienti con demenza multi-infartuale." (Comparative study on acquistion and retention curves in patients with Parkinson's disease and with multi-infartual dementia). Bollettino di Psicologia Applicata, 189, 15-22, 1989

M. Fioravanti, F. Di Cesare.
"Memoria a lingo termine e modalita' differenziate di acquisizione." (Long-term memory and diffferentiated acquisition modes) Bollenttino di Psicologia Applicata, 186, 13-20, 1988

M. Fioravanti, F. Di Cesare.
"Malattie respiratorie croniche e relazione con le capacita' di vita quotidiana dei pazienti: rassegna critica delle modalita' di valutazione." (Chronic obstructive pulmonary disease and relationship with the daily life competence of patients: review of the assessment procedures). Archivo Monaldi, 6, 463-473, 1988

M. Fioravanti, F. Di Cesare, L. Ramelli, R. La Torre, A. Nicastro, S. Messinetti, R. Lazzari.
"Pre-surgery information and psychological adjustment to enterostomy." The Italian Journal of Surgical Sciences, 18, 1, 55-61, 1988.

CONFERENCES, SYMPOSIA AND OTHER SCIENTIFIC PUBLICATIONS

International Society of CNS clinical trials & methodology, Autumn Meeting, Barcelona, 5-7- October 2023
Franco Di Cesare, Cristiana Di Carlo, Sara Grossi, Leonardo Di Cesare
"A Semantic Scale Analysis of Instruments Intended to Evaluate Psychedelic Experience in Clinical Trials." 6 October 2023.

Amir Inamdar, Joyce Tsai., **Franco Di Cesare**, et al. on behalf of the International Society of CNS for clinical trials and methodology (ISCTM)
"Response to the FDA request for comments regarding the draft guidance Psychedelic Drugs: Considerations for Clinical Investigations, Guidance for Industry." 23 August 2023.

Adam Butler, **Franco Di Cesare**, Joan Fallon, Debra Hoffmeyer et al. on behalf of the International Society of CNS for clinical trials and methodology
"Response to the FDA request for comment regarding the guidance document: Considerations for the Design and Conduct of Externally Controlled Trials for Drug and Biological Products Guidance for Industry." 1 May 2023.

Richard Keefe, Michael Sand, Debra Hoffmeyer, **Franco Di Cesare** et al. on behalf of the International Society of CNS for clinical trials and methodology
"Response to the FDA request for comment regarding the guidance document: Digital Health Technologies for Remote Data Acquisition in Clinical Investigations Guidance for Industry, Investigators, and Other Stakeholders." 22 March 2022.

International Society of CNS clinical trials & methodology, Autumn Meeting, Virtual Venue, 21st-25th September 2020
Franco Di Cesare, Cristiana Di Carlo, Leonardo Di Cesare
"Development of a Cognitive Ability Assessment Tool (CAAT) for use in paediatric clinical trials in Sub-Saharan countries."

International Society of CNS clinical trials & methodology, Autumn Meeting, Virtual Venue, 21st-25th September 2020
Franco Di Cesare, Cristiana Di Carlo, Leonardo Di Cesare
"Development of a Symbol Cancellation Test (SCT) for use in paediatric clinical trials in Sub-Saharan countries."

International Society of CNS clinical trials & methodology, Autumn Meeting, Copenhagen, 5th-7th September 2019
Franco Di Cesare, Cristiana Di Carlo, Leonardo Di Cesare, Kalima Kalima, Mwanza-Kabaghe Sylvia, Nkole Lisa, Kawatu Nfawama, Somwe Somwe, Ciccone Ornella
"New paediatric cognitive assessment methods for epilepsy clinical trials in middle-lower and low - income developing countries".

Atul Mahableshwarkar and Debra Hoffmeyer **Franco Di Cesare** et al. on behalf of International Society for CNS Clinical Trials and Methodology (ISCTM) welcomes this opportunity
"Response to the FDA request for comment regarding the guidance document: Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry." 6 August 2019.

International Society of CNS clinical trial & methodology, Autumn Meeting, Paris, 31 Aug – 2 Sept 2017

Franco Di Cesare and Cristiana Di Carlo

"Considerations on the conceptual framework and content validity of the Quality of Social Life Questionnaire (QoSL-Q), a patient reported outcome instrument to evaluate treatment response in clinical trials".

International Society of CNS clinical trials & methodology, Autumn Meeting, Paris, 31 Aug - 2 Sept 2017

Franco Di Cesare , Cristiana Di Carlo, and Mario Fioravanti

Profiling cognitive impairment in recovered Major Depressive Disorder. Considerations on clinical characterisation of the study population and on unmet diagnostic needs."

International Society of CNS clinical trials & methodology, 12th Annual Meeting, Washington D.C. 16-18 February 2016

Franco Di Cesare and Michelle Stewart

"Advancing trial design methodology to evaluate drug treatment effect on suicidal ideation and behavior."

International Society of CNS Clinical Trials & Methodology (ISCTM) - Consensus Meeting on Methodological Considerations on suicide assessment and clinical trial design, Arlington, USA, 17-18 November 2015

Franco Di Cesare on behalf of the ISCTM Working Group on design clinical studies and development programs for regulatory approval of medicines to treat suicidal ideation and behaviour.

"Design and methodology of suicide ideation and behaviour treatment studies."

British Neuroscience Association, Festival of Neuroscience, London, 7-10 April 2013

Franco Di Cesare, Cristiana Di Carlo

"LBR Memory Test: A new method to evaluate cognitive function in clinical and research settings." British Neurosci. Assoc. Abstr. Vol. 22: P476, 2013

British Neuroscience Association, Festival of Neuroscience, London, 7-10 April 2013

Franco Di Cesare, Cristiana Di Carlo

"Encoding and retrieval deficits as early markers of cognitive impairment in Parkinson's Disease." British Neurosci. Assoc. Abstr. Vol. 22: P845, 2013

Biomarkers Summit, London, February 1-2, 2010

F. Di Cesare

"Predictive biomarkers for mental health conditions."

3rd National Congress of the Italian Society of Psychology of Aging, Brescia, 13-14 November 2009

F. Di Cesare

"Is depression a precursor of dementia in the elderly?"

13th Congress of the European Federations of Neurological Societies EFNS, 12-15 September 2009, Florence, Italy
F. Di Cesare, *D. D'Ilario, M. Fioravanti*
"Memory as early marker of cognitive decline."

13th Congress of the European Federations of Neurological Societies EFNS, 12-15 September 2009, Florence, Italy
F. Di Cesare, *M. Novelli, C. Di Carlo, M. Fioravanti*
"A new computerized memory test to evaluate early cognitive decline and treatment response."

9th International Conference Alzheimer's/Parkinson's Disease, Prague, 11-15 March 2009
F. Di Cesare, C. Di Carlo, M. Fioravanti
"A clinical method to evaluate memory and semantic organisation in clinical research."

5th Annual Scientific of the International Society for CNS Clinical Trials & Methodology, Arlington, 3-5 March 2009
F. Di Cesare, C. Di Carlo, D. Kirola-Bugarski, M. Fioravanti
"Memory measures as biomarkers in psychiatric drug research."

i3 Innovation Series, December 2008
F. Di Cesare, D. Kirola-Bugarski, V. Sutton
"Biomarker-driven clinical drug development for innovative psychotherapeutics."

Biomarkers Europe 2008, Wien, 10-11 November 2008
F. Di Cesare, C. Di Carlo, M. Fioravanti
"A clinical method to evaluate memory and semantic organisation in drug research."

VI Convegno Nazionale Societa' Italiana di Neurogeriatria, Padua, 15-16 June 1996
(VI National Congress of the Italian Neurogeriatrics Association)
F. Di Cesare
"The cholinergic approach to the treatment of Alzheimer's disease".

Paneuropean Congress of Neurology, Wien, 5-8 December 1991
M. Fioravanti, **F. Di Cesare**
"Assessment of memory changes in therapeutic clinical trials of aging patients with early signs of cognitive decline".

XCII Congresso Nazionale della Societa' Italiana di Medicina Interna, Roma, 15-18 Ottobre 1991
(XCII National Congress of the Italian Society of Internal Medicine, Rome 15-18 October 1991)
F. Di Cesare, C. Sartini, E. Malacco
"Deficit cognitivi nel diabete non-insulino-dipendente: gli effetti del trattamento con diidroergocristina".
(Cognitive deficits in Non-Insulin-Dependent Diabetes: the effects of treatment with dihydroergocristine).

International Symposium on Drugs and Memory, Siena, 5-9 October 1991
M. Fioravanti, **F. Di Cesare**
"Proposal of a method for clinical assessment of pharmacological effects on memory: the Memory Efficiency Test".

XXI Congresso Nazionale AIPO (Ischia, 11-14 Settembre 1991)
F. Di Cesare, G. Girbino, G. Zavattini
"Associazione carbocisteina-sobrerolo e qualita' di vita in pazienti con bronchite cronica."
(Carbocysteine-sobrerol and quality of life in patients with chronic bronchitis)

V Congress of the International Psychogeriatrics Association, Rome, 19-23 August 1991
M. Fioravanti, **F. Di Cesare**
"Proposal for a method of memory evaluation in the chronic degenerative pathologies of the aging brain".
XII Congress of the International Society of Psychoneuroendocrinology – Life processes and events: psycho-neuro-endocrinological mechanisms of adaptation, Siena, 17– 23 June 1991
F. Di Cesare
"Dihydroergocriptine in the treatment of the premenstrual syndrome".

II International Symposium of the Working Group on pharmacology of dizziness. Florence 13–15 May 1991
F. Di Cesare, A.Poletti, F. Manfrin, M. Manzoni, E. Mira
"Effects of dihydroergocristine on visual-vestibular originated ocular movements. Double-blind placebo controlled clinical trial in patients with dizziness due to cerebrovascular disorders".

Convegno Nazionale su farmaci e reazioni avverse – Implicazioni clinico-diagnostiche ed I programmi di valutazione e controllo, Taormina, 5-6 April 1991
(I National Congress on drug and drug adverse reactions. Clinical and diagnostic implications and procedures of assessment and control. Taormina, 5–6 April 1991
F. Di Cesare
"Validita' clinica di misure di qualita' di vita nella malattia respiratoria cronica: il Sickness Impact Profile."
(Clinical validity of measures of quality of life in chronic respiratory diseases: the Sickness Impact Profile.)

International Conference "Brain and Immunity", Naples, 25– 26 March 1991
M.Fioravanti, **F. Di Cesare**
"Ergot-alkaloids and the treatment of cognitive deficits in cerebro-vascular disease."

2° Convegno Nazionale Informatica e Neuroscienze, Rome, 14 – 16 March 1991
(2nd National Congress on Informatics and Neurosciences, Rome, 14 – 16 March 1991)
M. Fioravanti, **F. Di Cesare**
" La valutazione dell'efficienza mnesica in pazienti con disturbi cerebrovascolari cronici: un approccio multidimensionale allo studio delle funzioni di memoria." (Assessment of memory efficiency in patients with chronic cerebro-vascular disease: a multidimensional approach to the study of memory functions).

International Psychogeriatrics Association Workshop – Assessment in psycho-geriatrics, Modena, 17-19 May 1989)
M. Fioravanti, **F. Di Cesare**
" Clinical assessment of objective memory in the aged: is it enough to transfer experimental techniques in the clinical domain?"

2nd European Conference "Improving the quality of hospital care: the psychologist's contribution"
Rome, 21 – 23 September 1989
M. Fioravanti, **F. Di Cesare**
"Psychological adjustment and rehabilitation to enterostomy."

International Multiple Sclerosis Conference. An update on Multiple Sclerosis, Rome, 11–17 September 1989
M. Fioravanti, **F. Di Cesare**
" A proposal of utilization of the subjective memory assessment in Multiple Sclerosis: an index of adjustment or decay?"

9th International Symposium on Parkinson's disease, Jerusalem, 3 – 5 June 1988
M. Fioravanti**, F. Di Cesare**, S. Ruggeri, L. Sibilla, E. Martignoni, A. Carta, G. Nappi, A. Agnoli
"Cognitive deficit in Parkinson's disease. A comparative evaluation of different methods of assessment for memory functions."

XXIV International Symposium of Applied Military Psychology, Toronto, 30 – 3 June 1988
F. Di Cesare, S. Tomassini, M. Laurenti
"Social factors and psychological adjustment to military life in adolescents."

1° Congresso Nazionale di Riabilitazione medico-chirurgica, Copanello, 11-13 Giugno 1987
(1st National Congress on Medical and Surgical rehabilitation, Copanello, 11–13 June 1987)
M. Fioravanti, **F. Di Cesare**, F. La Torre, A. Nicastro, S. Messinetti, R. Lazzari
"Adattamento psicologico e riabilitazione in pazienti enterostomizzati." (Psychological adjustment and rehabilitation in patients with enterostomy)

AUTHENTICATION

The information contained in this document is accurate to the best of my knowledge.

_____ 29 September 2023
Signature (Franco Di Cesare)