CV Short Form

Name:	Filippo Missiroli MD
Registration Details:	**Ordine provinciale di Roma dei medici e degli odontoiatri. N M48112**
Qualifications:	***Aggregate Professor*** at University of Rome Tor Vergata". Functional Area: Ophthalmic Diseases.
Degree(s) and Date(s):	*1996* Bachelor's Degree in Medicine - University of Rome La Sapienza, Summa cum Laude *2000* *ophthalmology residency* University of Rome La Sapienza Summa cum Laude *2001* *clinical and research fellowship on cornea and external diseases (UCSD La Jolla CA)*
Job address:	**UNIT PATOLOGIE OCULARI CRONICHE DEGENERATIVE** **CENTRO DI RIFERIMENTO REGIONALE E CLINICAL TRIAL CENTER PER LA DIAGNOSI E TERAPIA DELLE PATOLOGIE RETINICHE CECITANTI** **Fondazione Policlinico Tor Vergata** **viale Oxford 81, 00133 Roma, Italy.**
Working Experience:	*Since 2001: physician at* Policlinico di Tor Vergata
Clinical Research Experience:	Details of clinical studies performed following "ICH/GCP" and local laws. (VIEW2 Investigator's Meeting in Rome 24-26 Jan 2008) and local laws. ***RETAIN*** Investigator's Meeting in Rome 31 Aug-1 Sep 2010 **FOVEA 2304** Investigator's Meeting in Paris 27-29 Mar 2011 **18 May 2012 Certification Good Clinical Practice (GCP)** **for Investigator TFS Academy** **20 Jul 2022 Investigator Site Personnel ICH GCP Training** **Certificate Transcelerate** **Changes for site personnel working on Clinical research Studie** **2000/2004 Co-investigator** CNR Strategic Project "Robotics in Surgery" Ocular Microsurgery Operating Unit . **2006/2007 Co- investigator:** Phase IV study. Selective inhibition of VEGF in late stage CNV **2006/2007 Co-investigator:** Safety and efficacy monitoring of **"off label"** bevacizumab ITV on CNV, CSMO and neovascular glaucoma (AIFA) **2008 –Co-investigator VIEW 2** : Vascular Endothelial Growth Factor (VEGF) Trap-Eye : Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD) **2009 - Co-investigator** : "Case-Crossover Study of PDE5 Inhibitor Exposure as a Potential "Trigger Factor" for Acute NAION" **2010- Sub Investigator GALILEO:**Vascular Endothelial Growth Factor (VEGF) Trap-Eye Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO) **2010 –Sub Investigator OPH1001:** A phase 2, Randomized, double-masked, controlled trial to establish the safety and efficacy of intravitreous injections of E10030 (anti-PDGF pegylated aptamer) given in combination with Lucentis® in subjects with neovascular age-related macular degeneration

2010 – Sub Investigator RETAIN : Randomized, double masked, active controlled, phase 3 study of the efficacy, safety, and tolerability of repeated doses of an anti-VEGF agent, to compare anti-VEGF agent to laser treatment, in subjects with DME.

2011 –Sub Investigator FOVEA2304 ; "A 6-month, Phase II, Double-masked, Multicenter, Randomized, Placebo-controlled, Parallel Group Study to Assess the Safety and Efficacy of Topical Administration of Two Concentrations of FOV2304 (1% and 2%) Twice Daily for the Treatment of Center-involving Clinically Significant Macular Edema Associated with Diabetic Retinopathy"

2011 – Sub Investigator VIVID study a randomized, double masked, active controlled, phase III study of the efficacy and safety of repeated doses of intravitreal VEGF Trap-Eye in subjects with diabetic macular edema.

2012 –Sub Investigator PRIDE; Programma in aperto, multicentrico, in pazienti con diminuzione visiva causata dall'edema maculare diabetico per i quali non esistano adeguate alternative terapeutiche

2012- Sub Investigator CRYSTAL; A 24-month, phase IIIb, open-label, single arm, multicenter study assessing the efficacy and safety of an individualized, stabilization criteria-driven PRN dosing regimen with 0.5-mg ranibizumab intravitreal injections applied as monotherapy in patients with visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO)

2012- Sub Investigator BRIGHTER; A 24-month, phase IIIb, open-label, randomized, active controlled, 3-arm, multicenter study assessing the efficacy and safety of an individualized, stabilization-criteria-driven PRN dosing regimen with 0.5-mg ranibizumab intravitreal injections applied as monotherapy or with adjunctive laser photocoagulation in comparison to laser photocoagulation in patients with visual impairment due to macular edema secondary to branch retinal vein occlusion (BRVO)

2013- Physician ALLERGAN ;A Multicenter, Open-label, Randomized Study Comparing the Efficacy and Safety of
700 µg Dexamethasone Posterior Segment Drug Delivery System (DEX PS DDS) toRanibizumab in Patients With Diabetic Macular Edema

2014- Sub Investigator TWEYES ; Studio interventistico, multicentrico, prospettico, in aperto, con un solo gruppo di trattamento, della durata di 12 mesi per valutare la sicurezza e la tollerabilità di ranibizumab 0.5 mg in pazienti affetti da wAMD mono/bilaterale in occhi con BCVA inferiore a 2/10 e/o patologia del secondo occhio

2014- Sub Investigator PROMETHEUS; A 12-month, randomized, double-masked, sham-controlled, multicenter study to evaluate the efficacy and safety of 0.5 mg ranibizumab intravitreal injections in patients with
visual impairment due to vascular endothelial growth factor(VEGF) driven macular edema (ME

2014- Sub Investigator OLIMPIC; A 12-month, open-label, interventional, multicentre study to investigate the current criteria driving re-treatment with ranibizumab upon relapse in patients with visual impairment due to choroidal neovascularization secondary to pathologic myopia

2014- Sub Investigator OPH1002 ECLIPSE: A phase 3, Randomized, double-masked, controlled trial to establish the safety and efficacy of intravitreous administration of fovista (anti-PDGF pegylated aptamer) administered in combination with Lucentis® compared to Lucentis in monotherapy in subjects with subfoveal neovascular age-related macular degeneration.

2015- Sub Investigator CHROMA: A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-MASKED, SHAM-CONTROLLED STUDY OF EFFICACY AND SAFETY OF 10 mg LAMPALIZUMAB INTRAVITREAL INJECTIONS ADMINISTERED EVERY 30 OR 45 DAYS TO PATIENTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION.

2015- Sub Investigator OPH1004: A PHASE 3 RANDOMIZED, DOUBLE-MASKED, CONTROLLED TRIAL TO ESTABLISH THE SAFETY AND EFFICACY OF INTRAVITREOUS ADMINISTRATION OF FOVISTATM (ANTI PDGF-B PEGYLATED APTAMER) ADMINISTERED IN COMBINATION WITH EITHER AVASTIN® OR EYLEA® COMPARED TO AVASTIN® OR EYLEA® MONOTHERAPY IN SUBJECTS WITH SUBFOVEAL NEOVASCULAR AGE-RELATED MACULAR DEGENERATION

2015- sub Investigator OPH1008: Role of Multimodal Imaging in the Evaluation of Anatomic Alterations in Neovascular Age-Related Macular Degeneration (AMD) Subjects: 18 Month Phase 2a Open Label Study of Fovista® (Anti-PDGF Therapy) Administered in Combination with Anti-VEGF Therapy

2016- Sub Investigator OBTAIN: A 36 month observational study to describe the long-term efficacy and safety of ranibizumab 0.5 mg treatment in patients with visual impairment due to choroidal neovascularization (CNV) secondary to pathologic myopia (PM)

2016- Sub Investigator SEQUOIA: Safety and Efficacy of Abicipar Pegol (AGN-150998) in Patients With Neovascular Age-related Macular Degeneration

2016- Sub Investigator AZURE: An open-label, randomized, active-controlled,parallel-group, Phase-3b study of the efficacy, safety, and tolerability of 2 mg aflibercept administered by intravitreal injections using two different treatment regimens to subjects with neovascular age-related macular degeneration (nAMD)

2016- Sub Investigator AQUA. Open-label Phase-4 study to examine the change of vision-related quality of life in subjects with diabetic macular edema (DME) during treatment with intravitreal injections of 2 mg aflibercept according to EU label for the first year of treatment.

2016- Sub Investigator HARRIER RTH258: A Two-Year,Randomized, Double-Masked, Multicenter, Two-Arm Study Comparing the Efficacy and Safety of RTH258 6 mg Versus Aflibercept in Subjects with Neovascular Age-Related Macular Degeneration

2016- Sub Investigator COLUMBUS-AMD: Efficacy and safety of the biosimilaranibizumab FYB201 in comparison to the approved originator product Lucentis® in patients with neovascular age-related macular degeneration.

2016- Sub Investigator CENTERA: A multi-center, single-arm, interventional Phase IV study to evaluate the management of central retinal vein occlusion (CRVO) using a Treat and Extend (T&E) regimen of intravitreal (IVT) aflibercept.

2018- Sub Investigator OPHTEA : A dose-ranging study of intravitreal OPT-302 in combination with ranibizumab, compared with ranibizumab alone, in participants with wet AMD

2019- Sub Investigator OPH2005 :
A PHASE 2B RANDOMIZED, DOUBLE-MASKED, CONTROLLED TRIAL TO ESTABLISH THE SAFETY AND EFFICACY OF ZIMURA™ (COMPLEMENT C5 INHIBITOR) COMPARED TO SHAM IN SUBJECTS WITH AUTOSOMAL RECESSIVE STARGARDT DISEASE

2019 Sub Investigator RHINE: A phase III, multicenter, randomized, double-masked, active comparator–controlled study to evaluate the efficacy and safety of RO6867461 in patients with diabetic macular edema (RHINE)

2019 –Sub Investigator LUCERNE: A PHASE III, MULTICENTER, RANDOMIZED, DOUBLE-MASKED, ACTIVE COMPARATOR–CONTROLLED STUDY TO EVALUATE THE EFFICACY AND SAFETY OF FARICIMAB IN PATIENTS WITH NEOVASCULAR AGE-RELATED MACULAR DEGENERATION (LUCERNE)

2019 –Sub Investigator PANDA: A Multicenter, Double-Masked, Randomized, Dose-Ranging Trial to Evaluate the Efficacy and Safety of Conbercept Intravitreal Injection in Subjects with Neovascular Age-related Macular Degeneration

2019 –Sub Investigator RAPTOR: An Eighteen-Month, Two-Arm, Randomized, Double-Masked, Multi-center, Phase III Study Assessing the Efficacy and Safety of Brolucizumab versus Aflibercept in Adult Patients with Visual Impairment due to Macular Edema secondary to Branch Retinal Vein Occlusion (RAPTOR)" Protocollo CRTH258C2301

2021 - ongoing Sub Investigator PULSAR 20968: Randomized, Double-Masked, Active-Controlled, Phase 3 Study of the Efficacy and Safety of High Dose Aflibercept in Patients With Neovascular Age-Related Macula Degeneration

2021 - ongoing Sub Investigator AMGEN ABP 938; "A RANDOMIZED, DOUBLE-MASKED, PHASE 3 STUDY OF ABP 938 EFFICACY AND SAFETY COMPARED TO AFLIBERCEPT (EYLEA®) IN SUBJECTS WITH NEOVASCULAR AGERELATED MACULAR DEGENERATION"

2021- ongoing Sub Investigator GLEAM: A Prospective, Randomized, Double-masked, Active Comparator-controlled, Multi-center, Two-arm,Phase 3 Study to Evaluate the Efficacy and Safety of Intravitreal KSI-301 Compared with Intravitreal Aflibercept in Participants with Visual Impairment Secondary to Treatment-naïve Diabetic Macular Edema (DME)

2021- ongoing Sub Investigator ISEE 2008 GATHER2: A PHASE 3 MULTICENTER, RANDOMIZED, DOUBLE-MASKED, SHAM CONTROLLED CLINICAL TRIAL TO ASSESS THE SAFETY ANDEFFICACY OF INTRAVITREAL ADMINISTRATION OF ZIMURA™ (COMPLEMENT C5 INHIBITOR) IN PATIENTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION

2021- ongoing Sub Investigator BALATON a PHASE III, multicenter, randomized, double-masked, active comparator controlled study to evaluate the efficacy and safety of faricimab in patients with macular edema secondary to branch retinal vein occlusion

2021 **- Sub Investigator BEACON: A Prospective, Randomized, Double-masked, Active Comparator-controlled, Multi-center, Two-arm, Phase 3 Study to Evaluate the Efficacy and Safety of Intravitreal KSI-301 Compared with Intravitreal Aflibercept in Participants with Visual Impairment Due to Treatment-naïve Macular Edema Secondary to Retinal Vein Occlusion (RVO)**

2022 - Sub Investigator IMAGINE: One year, single arm, open label, multicenter, phase IV study using multimodal imaging to guide disease activity assessment through innovative early predictive anatomical biomarkers of fluid resolution in wAMD patients treated with brolucizumab

2023 ongoing Sub Investigator ALXN 2040-GA-201: Studio di fase 2, in doppio cieco, controllato con placebo, per la determinazione dell'intervallo di dosaggio di Danicopan (ALXN2040) in pazienti con atrofia geografica (AG) secondaria a degenerazione maculare legata all'età (DMLE)

2023 - ongoing Sub Investigator ISEE 2009 OLE: A PHASE 3 MULTICENTER, RANDOMIZED, DOUBLE-MASKED, SHAM CONTROLLED CLINICAL TRIAL TO ASSESS THE SAFETY ANDEFFICACY OF INTRAVITREAL ADMINISTRATION OF ZIMURA™ (COMPLEMENT C5 INHIBITOR) IN PATIENTS WITH GEOGRAPHIC ATROPHY SECONDARY TO AGE-RELATED MACULAR DEGENERATION

2023-Sub-Investigator QUASAR 22153: Randomized, Double-Masked, Active-Controlled, Phase 3 Study of the Efficacy and Safety of Aflibercept 8 mg in Macular Edema Secondary to Retinal Vein Occlusion (RVO)

“I conducted clinical research according to CGP and I authorize the use of my personal data according to regulation UE 2016/679

Roma, 25 maggio 2024