CV Short Form

Name:	Grossi Massimo OD
Registration Details:	Ordine TSRM PSTRP di Roma, n°140, 18/02/2019
Qualifications:	Ophthalmology Assistant.
Degree(s) and Date(s):	1998 Bachelor's degree cum Laude in „Ortottica e assistenza in Oftalmologia" University of Rome Tor Vergata
Job address:	**UNIT PATOLOGIE OCULARI CRONICHE DEGENERATIVE** **CENTRO DI RIFERIMENTO REGIONALE E CLINICAL TRIAL CENTER PER LA DIAGNOSI E TERAPIA DELLE PATOLOGIE RETINICHE CECITANTI** Policlinico di Tor Vergata Università di Roma Tor Vergata, Viale Oxford 81, 00133 Roma, Italy.
Working Experience:	*Since 2005: Technician at* Policlinico di Tor Vergata *2006-2024* Coordinator degree course in "Orthoptist and Assistant of Ophthalmology *2006 -2024 Professor***:** *"Diagnostic Techniques Integrated Course"* of the Degree Course for Orthoptist and Assistant of Ophthalmology "Tor Vergata" University. 2018 Course „*Clinical tutor" at* Policlinico di Tor Vergata

Clinical Research Experience:

- 2009- Publication Indocyanine green enhanced subthreshold diode-laser micropulse photocoagulation treatment of chronic central serous chorioretinopathy.
  F. Ricci & F. Missiroli & F. Regine & M. Grossi & G. Dorin
  Graefes Arch Clin Exp Ophthalmol (2009) 247:597–607
  DOI 10.1007/s00417-008-1014-1
- 2009- Publication Is it the pegaptanib sodium injection therapy appropriate in patients with choroidal neo-vascularization secondary to age-related macular degeneration not responsive or not eligible to Photodynamic Therapy ?
  F.Ricci, F. Missiroli, C.Cedrone, M.Grossi and F. Regine
- 2017-Indocyanine green angiography and Optical Coherence Tomography Angiography of Choroidal Neovascularization in Age-related Macular Degeneration. C. Eandi, A. Ciardella, MC Parravano, F. Missiroli, C. Alovisi, C. Veronese, MC. Morara, M. Grossi, G.Virgili, and F. Ricci
- 24 Oct 2017 MASTER' S DEGREE IN CLINICAL RESEARCH

Details of clinical studies performed following "ICH/GCP" (**VIEW2** Investigator's Meeting in Rome 24-26 Jan 2008 and **GALILEO** Investigator's Meeting in Rome 16-17 Oct 2009 and local laws.

ICH/GCP training performed on 29 December 2009, during VIEW2 monitoring visit.

OPHOTHOTECH **Oph 1001** Investigator's Meeting in Berlin 3 -4 Jun 2010

RETAIN Investigator's Meeting in Rome 31 Aug-1 Sep 2010

VIVID **VEGF Trap-Eye in DME 91745** Investigator's Meeting in Prague 2 - 4 Mar 2011

FOVEA 2304 Investigator's Meeting in Paris 27-29 Mar 2011

OPH 1002 ECLIPSE Investigator's Meeting in London 25-26 Apr 2014

ROCHE CHROMA Investigator's Meeting in Vienna 28 -30 Jan 2015

ROCHE LUCERNE Investigator's Meeting in Amsterdam 22-23 May 2019

07 02 2015 Certification Good Clinical Practice (GCP) E- learning Training Novartis

11 02 2015 Certification Good Clinical Practice" Minimum Criteria for ICH E6 GCP Investigator Site Personnel Training, Identified by TransCelerate BioPharma Inc.

22 Mar 2018 NIDA Clinical Trials Network, GCP Certificate

03 Dec 2018 Investigator Site Personnel ICH GCP Training Certificate **Transcelerate**

20 Mar 2019 Investigator Site Personnel ICH GCP Training Certificate **Transcelerate**

22 Jan 2020 Investigator Site Personnel ICH GCP Training Certificate **Transcelerate**

22 Jul 2021 Certificate The Global Heath Network ICH GCP E6 (R2)

1) 2006/2007 Co- investigator: Phase IV study. Selective inhibition of VEGF in late stage CNV

2) 2006/2007 Co-investigator: Safety and efficacy monitoring of **"off label"** bevacizumab ITV on CNV, CSMO and neovascular glaucoma (AIFA)

3) 2008 – 2010 Study Coordinator **VIEW 2** : Vascular Endothelial Growth Factor (VEGF) Trap-Eye : Efficacy and Safety in Wet Age-Related Macular Degeneration (AMD)

4) 2010- Study Coordinator GALILEO: Vascular Endothelial Growth Factor (VEGF) Trap-Eye Investigation of Efficacy and Safety in Central Retinal Vein Occlusion (CRVO)

5) 2010 –Study Coordinator 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

6) 2010–Study Coordinator 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.

7) 2011–Study Coordinator 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"

8) 2011 –Study Coordinator VIVID-DME; 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

9) 2012 –Study Coordinator PRIDE; Programma in aperto, multicentrico, in pazienti con diminuzione visiva causata dall'edema maculare diabetico per i quali non esistano adeguate alternative terapeutiche

10) 2012- Study Coordinator 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 0.5mg ranibizumab intravitreal injections applied as monotherapy in patients with visual impairment due to macular edema secondary to central retinal vein occlusion (CRVO)

11) 2012- Study Coordinator 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)

12) 2013- Study Coordinator ALLERGAN ;A Multicenter, Open-label, Randomized Study Comparing the Efficacy and Safety of 700 μg Dexamethasone Posterior Segment Drug Delivery System (DEX PS DDS) to Ranibizumab in Patients With Diabetic Macular Edema

13) 2014- Study Coordinator 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

14) 2014- Study Coordinator 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

15) 2014- Study Coordinator 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

16) 2014- Study Coordinator 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.

17) 2015- Study Coordinator 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.

18) 2015- Study Coordinator 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

19) 2015- Study Coordinator 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

20) 2016- Study Coordinator SEQUOIA: Safety and Efficacy of Abicipar Pegol (AGN-150998) in Patients With Neovascular Age-related Macular Degeneration

21) 2016- Study Coordinator LMG324: A randomized, open-label single ascending dose and double-masked, ranibizumab controlled, safety, tolerability,and efficacy study of intravitreal

LMG324 in subjects with neovascular age-related macular degeneration

22) 2016- Study Coordinator 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)

23) 2016- Study Coordinator VIOLET: An open-label, randomized, active-controlled, parallel-group, Phase-3b
study of the efficacy, safety, and tolerability of three different treatment regimens of 2 mg Eylea administered by intravitreal injections to subjects with diabetic macular edema (DME)

24) 2016- Study Coordinator 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)

25) 2016- Study Coordinator 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

26) 2016- ongoing Study Coordinator 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

27) 2016- Study Coordinator COLUMBUS-AMD: Efficacy and safety of the biosimilar ranibizumab FYB201 in comparison
to the approved originator product Lucentis® in patients wit neovascular age-related macular degeneration.

28) 2016- Study Coordinator 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.

29) 2018- Study Coordinator OPHTEA : A dose-ranging study of intravitreal OPT-302 in combination with Ranibizumab, compared with Ranibizumab alone, in participants with wet AMD

30) 2019- Study Coordinator 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

31) 2019 –Study Coordinator 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)

32) 2019 –Study Coordinator 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)

33) 2019 –Study Coordinator 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

34) 2019 –Study Coordinator 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 CRTH258C230

35) 2021 - ongoing Study Coordinator 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

36) 2021 - Study Coordinator 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"

37) 2021- Study Coordinator 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)

38) 2021- Study Coordinator 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

39) 2021- Study Coordinator 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

40) 2021 - Study Coordinator 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)

41) 2022 - Study Coordinator 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

42) 2023 ongoing Study Coordinator 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)

43) 2023 - ongoing Study Coordinator 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

44) 2023 - ongoing Study Coordinator QUASAR BAY 86-5321/22153 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)

International certifications for imaging: Clinical Trials VIEW2, GALILEO, FOVEA, AMGEN:

- Digital Angiography Reading Center DARC
  460 Park Avenue
  Suite 443
  New York, NY 10022 USA
  Phone +1+212-935-3039
  Fax +1+212-935-8775

International certifications for imaging: Clinical Trials OPH1001, OPH1002 ECLIPSE, OPH1004, GATHER2, ISEE2009 OLE

- The OCT Reading Center at Duke
  2200 West Main Street, Suite 220
  Durham, North Carolina USA 27705
  (919) 286-6575
  Fax (919) 286-6586

International certifications for imaging: Clinical Trials VIEW2, GALILEO, VIVID, HARRIER, LUCERNE, RHINE, BALATON, GLEAM, BEACON

- Vienna Reading Center
  Department of Ophthalmology
  Medical University of Vienna
  ANNA SPIEGEL FORSCHUNGSGEBAEUDE
  7th floor, room no.: 25.07.039

International certifications for imaging: Clinical Trials ALLERGAN, CHROMA, OPH2005, PANDA, PULSAR

- Doheny Image Reading Center (DIRC)

  Doheny Eye Institute, Los Angeles, California USA

  Phone: 323-442-6393

International certifications for imaging: Clinical Trials BAYER AZURE, AQUA, VIOLET. KALAHARI, QUASAR

- CORC – Coimbra Ophthalmology Reading Center

  AIBILI, Azinhaga de Santa Comba – Celas
  3000-548 Coimbra, Portugal
  Tel: +351 239 480 135

International certifications for imaging: Clinical Trials PROMETHEUS, CENTERA, RAPTOR, RAVEN

- BPRC Bern Photographic Reading Center

  Universitätsklinik für Augenheilkunde
  Inselspital
  Freiburgstrasse
  CH-3010 Ber

International certifications for imaging: Clinical Trial ROBIN

- OIRRC

  333 W Maude Ave. #108 Sunnyvale, CA 94085
  International certifications for imaging: Clinical Trial COLUMBUS

- GRADE Reading Center

  Department of Ophthalmology, University of Bonn, Germany

  Phone**:** +49 228 287 14813

International certifications for imaging: Clinical Trials SEQUOIA, PULSAR

- FPRC Fundus Photograph Reading Center

  Department of Ophthalmology and Visual Sciences

  University of Wisconsin – Madison, Wisconsin USA

  Phone**:** 608-410-0560

Certifications eCRF for Clinical Trials GALILEO, VIVID, HARRIER, CHROMA, SEQUOIA, AZURE, AQUA, VIOLET, PANDA, RAPTOR, AMGEN, PULSAR, GLEAM BEACON

- MEDIDATA RAVE Corporate Headquarters
  79 Fifth Avenue, 8th Floor
  New York, New York 10003
  USA

Certifications eCRF for clinical trials OPH1001, OPH1002, OPH1004.

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  helpdesk@iddi.com
  1-866-SOS-IDDI

Certifications eCRF for clinical trials VIEW2, RETAIN

- Perceptive Informatics Inc 900 Chelmsford St # 308, Lowell, MA 01851-8308,
- Stati Uniti +1 978-275-0062

Certifications eCRF for clinical trials FOVEA, CRYSTAL, BRIGHTER, PROMETHEUS, OPH1008, OPH2005, GHATER 2

- **ORACLE INFORM**
  Phase Forward Incorporated
  77 Fourth Avenue
  Waltham, MA 02451
  United States

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

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Date Signature