CLINICAL MANAGER
CLINICAL OPERATIONS

Maria Solinas, B.Sc.

EDUCATION

B.S., Biology Science, 2002
University of Milan, Italy

THERAPEUTIC EXPERIENCE

Circulatory: Acute Pulmonary Heart Disease
Dermatology: Complicated Bacterial
Digestive System: Crohn's Disease
Genitourinary: Contraception, Cystitis, Erectile Dysfunction (PADAM)
Hematology/ Oncology: Gastrointestinal Stromal Tumors, Myelofibrosis with Myeloid Metaplasia
Infections/Parasitic Diseases: Human Immunodeficiency Virus, Skin and Soft Tissue Infection (cBSSTI)
Musculoskeletal: Rheumatoid Arthritis
Nervous System/Sense Organs: Parkinson`s Disease

PROFESSIONAL EXPERIENCE

PPD Milan, Italy

*M-CM **	*2017-Present*
*AM-CM **	*2015-2017*
PCRA	*2013-2015*
SCRAII	*2012-2013*
SCRAI	*2007-2012*
CRAII	*2005-2007*

**Title change reflects position re-alignment*

Manager, Clinical Management: Manages, selects, trains, resources, coaches and performance management of respective staff, which may be inclusive of CRAs, PAs, RSMs and other clinical focused staff. Focuses on end results using metrics and key performance indicators to manage performance. May lead or contribute to initiatives that enhance the department's performance or lead to process improvement across PPD. Collaborates with Clinical Management senior management and executive staff on strategic planning and business development as required.

AM CM: Associate Manager, Clinical Management: Oversees daily line management responsibilities of assigned team. Serves as positive leadership and professional role model for respective staff, which may be inclusive of CRAs, PAs, RSMs and other clinical focused staff. Provides direct coaching and development support to operational teams. Ultimately responsible for effective resourcing, alignment, training and on-going professional and technical development for staff. Collaborates with Clinical Management senior management and executive staff on strategic planning and business development as required. Primary focus on line and performance management of team members. Acts as point-of-escalation regarding performance concerns and training needs to ensure adherence to PPD SOPs and WPDs. Works in collaboration with the leadership team for resourcing needs.

PCRA: Principal Clinical Research Associate on phase III, HIV trial in suppressed patients. Performed site initiation and interim monitoring visits. As Lead CRA, supported the Clinical Team Manager to review and approve interim monitoring visit reports, supervise CRA activities and act as a reference point for eCRF query management, Central Lab and CRAs. Involved in the preparation and presentation of practical hints for training CRAs new to the team.

PCRA/SCRAII: Principal Clinical Research Associate on a phase III, HIV trial in naïve patients. Performed interim monitoring and close-out visits.

PCRA/SCRAII: Principal Clinical Research Associate on a phase IIIb, HIV trial in suppressed patients. Performed interim monitoring visits.

PCRA/SCRAII: Principal Clinical Research Associate on a phase III, cBSSTI trial. Performed initiation, interim monitoring and close-out visits.

PCRA/SCRAII: Principal Clinical Research Associate on a prospective, observational, post-marketing Crohn's Disease trial. Maintained monthly contact calls with sites and performed close-out visits.

LT: Local Trainer: May prepare training materials; Delivers training and assesses participants.

RCC: Regulatory Compliance Co-coordinator: Co-ordinates Regulatory Compliance Review activities within Italy. Identifies mentors, assigns and advises RCR reviewers in the RCR process.

RCR: Regulatory Compliance Reviewer, appropriately trained to perform a final and independent quality control of essential documents required to start and maintain a clinical trial.

Accompanier: Authorised to conduct PAVs (Performance Assessment Visits) to provide ongoing training, evaluation and development of the PPD monitor.

SCRAI: Senior Clinical Research Associate on an Italian, phase II trial in Acute Pulmonary Heart Disease. Performed monitoring activities, initiation and interim monitoring visits. Responsible for 1 site. Participated in a meeting with Sponsor, Site and CTM. As Lead CRA, assisted the Clinical Team Manager and Project Manager to supervise and co-ordinate the clinical activities of CRAs within the team to ensure the clinical deliverables of the trial were met.

SCRAI: Senior Clinical Research Associate on an Italian, phase IIIb trial in Rheumatoid Arthritis. Performed start-up and monitoring activities, initiation and interim monitoring visits. Responsible for 9 sites.

SCRAI: Senior Clinical Research Associate on an Italian, phase II trial in Myelofibrosis Disease. Performed start-up and monitoring activities, initiation and interim monitoring visits. Responsible for 2 sites. Collaborated with involved vendors throughout the trial. Used Electronic Data Capture (EDC) systems.: eCRF, IVRS.

CRAII: Clinical Research Associate on an Italian, phase III trial in Parkinson's Disease. Performed start-up activities, pre-study, initiation and interim monitoring visits. Responsible for 9 sites. Used PPD's Query Direct system.

Schering S.p.A., Milan, Italy & Dimensione Ricerca S.r.l., Milan, Italy
CRA *2004-2005*

CRA: Clinical Research Associate on an Italian, phase IV trial in Partial Androgen Deficiency of Aging Males (PADAM). Performed initiation and monitoring visits. Responsible for 4 sites. During this trial, mentored 1 CRA new to the team.

CRA: Clinical Research Associate on an Italian, phase III trial in Oral Contraception. Performed interim monitoring visits. Responsible for 7 sites. During this trial, mentored 2 CRAs new to the team.

OPIS S.r.l, Milan, Italy *CRA* *2004-2004*

CRA: Clinical Research Associate on an Italian, phase IIIa trial in Cystitis. Performed initiation and interim monitoring visits for 16 sites. During this trial, mentored 3 CRAs new to the team.

CRA: Clinical Research Associate on an Italian, observational trial in Gastrointestinal Stromal Tumours (GIST). Performed initiation visits. Responsible for 9sites. During this trial, mentored 1 CRA new to the team.

University of Milan, Italy *Research Fellow* *2002-2004*

Research Fellow in the Dipartimento di Scienze Farmacologiche, Università Statale di Milano. Worked on a X-linked Adrenoleukodystrophy project.

PROFESSIONAL DEVELOPMENT

Completed PPD Clinical Foundation Programme, January 2006.

Further training while employed at PPD is available upon request.

Prior to PPD:

- February 10th ,2005: IMPACT Module 5 – Study Monitoring - (refresher course)
- January 25th, 2005, Milan: "New version IMPACT" (Organised by Schering S.p.A.)
- December 14th, 2004, Milan: "Good Clinical Practices and Audit" (Organized by Schering S.p.A.)
- February 2nd – 20th, 2004, Desio: course for CRA (Organised by OPIS. S.r.l) "Clinical Research procedures and Good Clinical Practices".

LANGUAGES

Mother tongue: Italian. Proficient in English.

CLINICAL TRIAL EXPERIENCE

Circulatory: A prospective, randomised, pilot trial to evaluate the effect of pre-operative Antithrombin supplementation on post-operative levels of Antithrombin in patients undergoing Cardiac Surgery with Cardiopulmonary Bypass.

Dermatology: A phase III, multi-centre, randomised, double-blind, comparative trial to evaluate the efficacy and safety of xxx (xxx mg every 8 hours) versus xxx plus xxx in the treatment of patients with Complicated Bacterial Skin and Soft Tissue Infections (cSSTI) with evidence of systemic inflammatory response or underlying comorbidities.

Digestive System: A European, registry, Crohn's Disease trial: A prospective, observational, post-marketing safety surveillance registry of patients treated with xxx® or standard therapy.

Genitourinary: An efficacy and safety of xx, extended-release, once-daily (OD) versus xx, immediate-release, twice-daily, both given for 7-14 days in patients with Complicated Urinary Tract Infections (cUTI): A prospective, randomised, double-bind, multi-centre trial. (Cystitis)

Genitourinary: A multi-centre, double-blind, randomised, placebo-controlled trial of xxx to evaluate the efficacy and safety in men presenting with typical symptoms of Partial Androgen Deficiency of Aging Males (PADAM) over a period of 6 months with 12 months open-label follow-up.

Genitourinary: A multi-centre, open, uncontrolled trial to investigate the efficacy and safety of an Oral Contraceptive containing in a 24-day regimen for 13 cycles in healthy female volunteers.

Hematology/Oncology: A multi-centre, observational trial in Gastrointestinal Stromal Tumours (GIST).

Hematology/Oncology: A phase II, prospective, randomised, multi-centre, double-blind, active-control, parallel-group trial to determine the safety of and to select a treatment regimen of trial drug either as single-agent or in combination with xxx to study further in patients with Myelofibrosis with Myeloid Metaplasia.

Infections/Parasitic Diseases: A phase IIIb, randomized, double-blind switch study to evaluate the safety and efficacy of xxx Fixed Dose Combination (FDC) in HIV-1 positive subjects who are virologically suppressed on xxx

Infections/Parasitic Diseases: A phase III, randomised, double-blind, switch study to evaluate xxx in HIV-1 positive subjects who are virologically suppressed on regimens containing xxx

Infections/Parasitic Diseases: A phase IIIb, randomised, open-label trial in HIV-1 infected, antiretroviral treatment-naïve adults.

Infections/Parasitic Diseases: A phase III, randomised, open-label trial to evaluate switching from regimens in virologically suppressed, HIV-1 infected patients.

Musculoskeletal: A phase IIIb, multi-centre trial with a 12-week, double-blind, placebo-controlled, randomised period followed by an open-label, extension phase to evaluate the safety and efficacy of xxx administered to patients with Active Rheumatoid Arthritis.

Nervous System/Sense Organs: A 39-week, randomised, double-bind, parallel-group, multi-centre trial to evaluate the effect of a fixed-dose sympathomimetic [adrenergic] agent (t.i.d.) vs. immediate release sympathomimetic [adrenergic] agent (t.i.d.) in patient with Parkinson`s Disease.

Maria Solinas
Clinical Manager
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