**Curriculum Vitae**

**Current Date: 19 July 2021**

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| **Name** | Isabel Soriano Paradinas |

| **Current Company Position** | |
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| 01Jul2021- Present<br><br>Associate Director, Clinical Project Scientist | • Scientific responsibilities will include internal activities such as interpreting clinical endpoints for topline results, participating in preparing Clinical Study Reports and in Disease Area Stronghold and Compound Development Team activities. External scientific collaborations will include interacting directly with academic investigators, coordinating clinical presentations at scientific meetings, and facilitating scientific publications in a timely manner.<br>• As Study Responsible Scientist (SRS), will work together with the Study Responsible Physician (SRP) and GCDO Trial Leader (GTL) in the Core Clinical Team to ensure the efficient initiation and execution of early phase clinical trials.<br>• Work within the cross-functional ED Clinical Team collaborating closely with the SRP and the ED Project Scientist Leader to plan, execute and oversee patient-oriented oncology ED clinical trials<br>• Participates in writing protocol synopses, full protocols, informed consent documents, and will help design Case Report Forms (CRFs) and other data collection tools.<br>• Provide input to the Statistical Analysis Plan, the Data Management Plan, and the Safety Management Plan.<br>• In collaboration with the SRP, prepare the Medical Review Plan.<br>• Participate in investigator meetings, pre-trial assessment visits (as needed) and site initiation visits.<br>• Participate in study start-up activities including site selection, review of vendors' scope of work contracts, timelines, and management of study close out activities.<br>• For ongoing clinical trials, the SRS will review all incoming clinical data in real time including patient screening results, PK/PD data, adverse events and other study endpoints and will perform medical review activities in collaboration with the SRP.<br>• Maintain adherence to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Good Clinical Practice (GCP) guidelines.<br>• Work closely with other key support areas including Global Clinical Operations, Translational Research, Medical Writing, Regulatory Affairs, Project Management, Biostatistics & Programming, and Clinical Pharmacology, and other allied support functions.<br>• Provide support to the Global Clinical Operations partners, including the GCDO Trial Leader, Local Trial Manager and Site Managers by working with clinical site staff as needed to resolve issues. |

| **Previous Experience** | |
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| 01Jul2020-<br>01Jul2021<br><br>Sr. Manager, Clinical Project Scientist | • Scientific responsibilities will include internal activities such as interpreting clinical endpoints for topline results, participating in preparing Clinical Study Reports and in Disease Area Stronghold and Compound Development Team activities. External scientific collaborations will include interacting directly with academic investigators, coordinating clinical presentations at scientific meetings, and facilitating scientific publications in a timely manner.<br>• As Study Responsible Scientist (SRS), will work together with the Study Responsible Physician (SRP) and GCDO Trial Leader (GTL) in the Core Clinical Team to ensure the efficient initiation and execution of early phase clinical trials.<br>• Work within the cross-functional ED Clinical Team collaborating closely with the SRP and the ED Project Scientist Leader to plan, execute and oversee patient-oriented oncology ED clinical trials<br>• Participates in writing protocol synopses, full protocols, informed consent documents, and will help design Case Report Forms (CRFs) and other data collection tools.<br>• Provide input to the Statistical Analysis Plan, the Data Management Plan, and the Safety Management Plan.<br>• In collaboration with the SRP, prepare the Medical Review Plan.<br>• Participate in investigator meetings, pre-trial assessment visits (as needed) and site initiation visits.<br>• Participate in study start-up activities including site selection, review of vendors' scope of work contracts, timelines, and management of study close out activities.<br>• For ongoing clinical trials, the SRS will review all incoming clinical data in real time including patient screening results, PK/PD data, adverse events and other study endpoints and will perform medical review activities in collaboration with the SRP.<br>• Maintain adherence to International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and Good Clinical Practice (GCP) guidelines.<br>• Work closely with other key support areas including Global Clinical Operations, Translational Research, Medical Writing, Regulatory Affairs, Project Management, Biostatistics & Programming, and Clinical Pharmacology, and other allied support functions.<br>• Provide support to the Global Clinical Operations partners, including the GCDO Trial Leader, Local Trial Manager and Site Managers by working with clinical site staff as needed to resolve issues. |
| 03Jan2019-<br>30Jun2020<br>Sr Trial Manager ED&CP | • Responsible for GTM and SM tasks depending on the studies assigned.<br>• Experience in hematology disease, such as Multiple myeloma, NLH and CLL.<br>• Responsible for study feasibility and site/lab assessments, providing recommendation of suitable sites for selection to participate in the trial. Ensures appropriate follow-up of pre-trial visit reports.<br>• Collaborates with the CPL, GTM, country TMs (if applicable), functional management and Protocol Owner to select final site list.<br>• Contributes input to the development of e.g. the Safety Monitoring Plan, Filing and Archiving Plan and Investigational Product documents at a country level or initiates development of these plans for trials to which no GTM is assigned.<br>• Leads and coordinates local trial team(s) activities in compliance with GCO Standard Operating Procedures (SOP), Work Instructions (WI) and applicable regulations. Leads project planning activities to meet recruitment targets and to deliver high quality data on time and within study budget. Including but not limited to: development of trial specific procedures and tools, recruitment planning, contingency and risk management, and budget forecasting (if applicable).<br>• Ensures that all SAEs/PQCs are reported within reporting timelines and documented as appropriate.<br>• Maintains and updates trial management systems (e.g. CTMS, eTMF/LAF, Trial Master Source and SharePoints sites). Uses study tools and management reports available to analyze trial progress<br>• Monitors country and overall study progress (if applicable) and initiates corrective and preventive actions when the trial deviates from plans and communicates study progress and issues to CPL, GTM, protocol owner and study management teams e.g. ensures appropriate documentation and follow-up related to protocol issue escalation.<br>• May submit requests for vendor services and may support vendor selection. Reviews and approves site and local vendor invoices as required.<br>• Other duties as assigned. |

| **Previous Experience** | |
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| Clinical Team Manager, PRA Health Sciences, Madrid, Jan 2017- Jan 2019 | • In liaison with the global clinical team, assist in the development of/independently lead strategic local trial execution plan and timeline commitments for a country/cluster.<br>• Oversee of the status of site budget and contract negotiations as well as the collection and review of essential documents.<br>• Oversee clinical team activities to achieve trial timelines and quality execution according to Sponsor standards and local regulations.<br>• Responsible for contracts reviewing, design of study tools and documents, review monitoring visit reports, protocol feasibilities and sites selection.<br>• Assistance in the identification of quality issues and in the implementation of corrective actions.<br>• Accountable for all submissions and communications to the relevant regulatory authorities.<br>Accomplishment: Recruitment for study CNTO1959PSO3009, reaching our recruitment goal in just 3 weeks, having a recruitment hold and pushing the clinical team to be able to continue the Spanish recruitment in order to get our expectations. |
| Lead Clinical Research Associate, Madrid<br>Mar2012-Jan2017 | • In liaison with the global clinical team, assist in the development of/independently lead strategic local trial execution plan and timeline commitments for a country/cluster Experience supporting CRA teams located in other European countries, such as Portugal, France and Italy. Oversee of the status of site budget and contract negotiations as well as the collection and review of essential documents. Oversee local clinical team activities to achieve trial timelines and quality execution according to Sponsor standards and local and international regulations. Trial budget management and follow up with responsible in country, mostly with Medical Affairs department. Serve as the initial contact/resource for fielding monitoring-related issues (via phone, email, and/or in person) for other CRAs on the project team. Responsible for the set-up, maintenance and filing of project-specific CRA tools. Responsible for the set up and maintenance of the Monitoring Plan<br>• May serve as Lead CRA on a project, acting as the primary contact for all monitoring- related questions for the monitoring team. Work in collaboration with the Clinical Trial Manager (CTM), Medical Monitor (MM), Data Manager (DM), and Biostatistician (BS) to define the Clinical Study Report (CSR) reportable categories, and/or additional protocol deviation categories. Attending project-related interdepartmental meetings as well as Sponsor teleconferences and face-to-face meetings when possible. Develop materials and present at project-specific meetings (e.g. investigator meetings), as appropriate. Conduct pre-study, initiation, monitoring, and close-out visits according to SOPs and GCP Ample experience in different therapeutic areas: Renal disease, Hypercholesterolemia in pediatrics, Neurology studies (Duchenne and Becker disease in pediatrics), Liver chronic disease, Tinnitus (Otolaryngology), Cutaneous T-Cell Lymphoma, Rheumatoid Arthritis |
| Sr. Clinical Research Associate, Grünenthal Pharma S.A., Madrid,<br>Jul 2011-Mar 2012 | Conducted monitoring visits at assigned sites for protocols Performed submissions and communications to Ethics Committees Held responsible for primary point of contact for clinical operations aspects of designated projects and developing successful working relationships with clients Provided support to the clinical operations study teams and participated in company initiatives Reviewed TMFs for inspection Performed team task duties, such as updating SOPs Therapeutic areas: Pain treatment (chronic malignant tumor-related pain and Rheumatoid artritis-related pain). |
| Sr. Clinical Research Associate, Madrid, Dec2010-Jun 2011 | Conducted monitoring visits as assigned sites Ensured studies were conducted in accordance with protocols, SOPs, GCP, and applicable regulatory requirements Therapeutic areas: Malignant Tumor of Breast (Phase III), Schizophrenia: antipsychotic agents (Phase III). |
| Clinical Research Associate, Madrid, Jul 2008-Dec 2010 | • Executed monitoring plans Ensured site GCP compliance Responsible for the sites Created trip reports Resolved issues and facilities open issue resolutions Performed self-enrollment and monitored safety sites Attended site qualification visits and conducted site initiations, routine, and close-out visits<br>• Therapeutic area: Demencia, area Neurology, (Phase III study). Experience in audits (Sep 2009). |
| Clinical Research Associate Fellowship, MSD, Madrid<br>Jan 2008-Jul 2008 | Performed monitoring and close-out visits Conducted complete Trial Master File management Gathered all documentation produced during the trial process Therapeutic areas: Papilloma virus vaccine, Osteoporosis, Hepatitis B vaccine and paediatric population (Phase III study), Oncology, Muscular weakness, HIV. |

| **Education** | |
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| 2017-2018 | **Master of Science in Clinical Trial Monitoring, Jun 2008** |

| Education | |
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| | Official College of Pharmacists – Madrid, Spain, Madrid, Madrid, SPAIN |
| 2001-2006 | **Pharmaceutical degree, Jul 2006**<br>Universidad de Alcalá, Alcalá de Henares, Madrid, SPAIN |

| Certification/Licenses |
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| **Pharmacy degree,** University of Alcala de Henares –, SPAIN<br>Acquired Date: Jul 2006 Expiration Date: Jan 2056 |
| **Certified Clinical Research Associate (CCRA),** Official College of Pharmacists – Madrid, Spain, SPAIN<br>Acquired Date: Jul 2008 Expiration Date: Jan 2056 |

| Presentations | |
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| Nov 2018 | Course of Monitoring Activities (AEFI) |

| Professional Memberships/Societies | |
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| **Year(s)** | **Position Held/Name of Association/Society** |
| 2017 - Present | Membership of AEFI (Asociación Española de Farmacéuticos de la Industria) |
| Nov 2018 | Coordination activities of Clinical Trials Group of AEFI |

| Computer Applications | |
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| TYPE | NAME |
| Central ECG & BP | Monitoring ERT |
| Central Imaging Services | Bioclinica |
| Central Lab Services | Medpace Lab, Covance, Q3,.. |
| Central Spirometry | Newcastle services |
| Clinical Sample Testing Services | Q3 |
| Clinical Staffing Services | TFS CRO |
| EDC / eDiary / e-PRO | Medidata, Oracle, Medpace EDC, InForm |
| IXRS | Clinphone, Medpace, Bracket |
| Translation Services | Celer, Interpret solutions, Okodia |

| Languages |
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| English Conversational, Reading, Writing, Medical records/ terminology High |
| Spanish Conversational, Reading, Writing, Medical records/ terminology High |

ISABEL SORIANO PARADINAS

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