

AIDA FERNANDEZ

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SUMMARY OF WORK EXPERIENCE IN DATA MANAGEMENT

- **2022- present. Clinical Data Scientist.** TFS for Almirall. Remote (Madrid)
Summary:
 - Oversight of the Data Management activities at the CROs
 - Start up: Lead review and approval of the Case Report Form (CRF), completion guidelines and other related documents. Review annotated documents, study metadata, trial definition SDTMs domains, Data Management Plan (coding, validation plan, SAE reconciliation between safety and clinical databases) vendor's technical specifications.
 - Conduct: Manage with the CRO to have data available for data visualization and analysis at the agreed timelines. Assessment of the database structure and study documentation review, evaluation of the data quality in ongoing basis. Coordination internal data review activities and follow-up or finding resolution with CRO.
 - Lock: Management of the database lock processes, review related database lock documentation (including approval of coding and SAE reconciliation), evaluation of the database quality before database lock approval.
 - Collaboration in the selection of the Contract Research Organizations (CROs).
 - Coordination of the timelines and processes of data management activities of the projects with the study team.
 - Follow-up on KPIs for overseeing quality and deliverables of CRO Data Management activities.
 - Provide technical advice on Data Management items to other departments or areas in the company.
- **2017- 2022. Data manager.** Sermes CRO. Madrid
- **2017** Research Project "Biothec-Ma: Teaching Biotechnology for Human Health, from the bench to the market". Oviedo University. March-June 2017
- **2016- 2017.** Cabueñes Hospital. Data manager. Celgene MEDI4736-MM-003 (FUSION MM-003) trial

• DATA MANAGEMENT, PROJECT MANAGEMENT SKILLS

- DM documentation: eCRF/CRF, eCRF/CRF guidelines, DMP, DMOP, DVS, DTA/DTS, ECS, eCRF UAT/ QC, CRO oversight, KPIs.
- CRO oversight/ communication CRO-Sponsor: review/follow up of CRO activities
- Review/reconciliation of external vendors data, AEs.
- Coding (MedDRA, WHO-drug)
- SDTM data review, Pinnacle21.
- CDISC/CDASH standards
- EDC: Medidata Rave, Viedoc, share crf, Xolomon
- Protocol deviations review.
- SOPs review/update
- DM TMF
- Clinical Trials phases I to IV
- Microsoft Office
- SAS, SAS JMP, Databricks (basic level)
- Coordinate, lead and perform clinical data management activities for assigned studies in accordance.
- Ensure timeliness of deliverables are met.
- Lead and facilitate all project team meetings CRO-Sponsor and internally.
- Certificate of good clinical practice

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- **Therapeutic Experience**

Dermatology. Acne. Hidradenitis Suppurativa. Atopic Dermatitis.

Several projects in CRO i.e. Arthritis, multiple myeloma, hypertension, condom test for premature ejaculation, fecal incontinence.

- **COURSES**

- **2019.** “Presente y Futuro del Data Management en Investigación Clínica”. Asociación Española de Farmacéuticos de la Industria (AEFI). Madrid, 23-Sep-2019.

OTHER WORK EXPERIENCE

Biologist.

- **2016- 2017.** Oviedo University. Neuroscience research.
- **2015- 2017.** Cabueñes Hospital. Data Manager. Myeloma database. (Asturias-Spain)
- **2008–2009.** AVALIA-T. Doing papers and research publications (Santiago de Compostela–Spain).
- **2010–2011.** ASPRA. Biology camps
- **2004–2004.** RENY PICOT. Laboratory Technician Microbiology. Microbiological tests in food(Asturias–Spain)

- **Biology skills**

- Techniques of Molecular Biology: DNA and RNA isolation, western, northern and southern blot, PCR.
- Techniques of immunology: ELISA.
- Optical microscopy techniques.
- Preparation of buffers and reagents for PCR.
- Techniques for DNA extraction from different types of samples (tissue, blood, sputum,...)
- Basic knowledge of Nuclear Magnetic Resonance and HPLC.

Camp Leader

- **2017-2017.** Depor Cantabria. English surf camp. English teacher and coach. (Asturias-Spain)
- **2014- 2017.** Futurines Kindergarten. Kindergarten assistant
- **2015-2015.** Depor Cantabria. English camp. English teacher and coach. (Asturias-Spain)
- **2014-2014.** Depor Cantabria. English camp. English teacher and coach. (Asturias-Spain)
- **2013-2013.** Planeta Piruleta, S.L. English camp. English teacher and coach. (Asturias-Spain)
- **2013-2013.** Out-of-school English camps. SyG Education. (Asturias-Spain).
- **2011–2012.** MOTIVA. Organizing holiday camps for children. (Asturias–Spain)
- **2011–2011.** CRUZ ROJA ESPAÑOLA. Coach of a Carnival camp.

Bus assistant

- **2011–2012.** MOTIVA. Bus assistant with disabled and children (Asturias–Spain)

Teacher

- **2008–2017.** extrasolar and support lessons (Asturias–Spain)

Sales Assistant

- **1996–2010.** EL ESTUCHE. Shop assistant.

EDUCATION

Further Education

- **2009 – 2010 MSc FOOD BIOTECHNOLOGY.** University of Oviedo, Spain. 2:1 equivalent.
- **2007 - 2008 PhD BIOLOGY.** University of Oviedo, Spain. Thesis: "Genetic alterations in the gene p53 and risk of lung cancer". Reading date: September 2008. 2:2 equivalent.
- **2006-2007 PGCE.** University of Oviedo. 2:2 equivalent.
- **2005-2007 DEA.** University of Oviedo, Spain. Research work: "Marker of susceptibility p53 Arg72Pro and risk of lung cancer". Reading date: June 2007. 2:2 equivalent.
- **1999-2004 – MSc BIOLOGY** - University of Oviedo, Spain. 1:1 equivalent.

Secondary Education

- **1995-1999 C.S.E. and BACH** in Science (equivalent to A-Levels), with subjects studied including biology, maths, physics, chemistry, technical drawing, French and English. Cesar Rodriguez high school, Grado, Spain.
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SCHOLARSHIPS

- **2005 - 2005 LEONARDO DA VINCI.** Institute of Biology of Leiden (Netherlands). Project: "Classification of species of *C. Roseus* based on the use of NMR and HPLC".
 - **2006 - 2007 IUOPA PREDOCTORAL SCHOLARSHIP.** Cancer Institute of Principado de Asturias.
 - **2007 SAHH GRANT.** Myeloma Monitor Project. Cabueñes Hospital. 2007
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CONFERENCES

- **2016** "Monoclonal antibodies in MM treatment". Gijón. 14-April-2016.
 - **2016** "Monoclonal antibodies in MM treatment". Gijón. 4-August-2016.
 - **2016** BAC 2016. La Laboral, Gijon 13, 14, 15-july-2016.
 - **2016** Celgene MEDI4736-MM-003 (FUSION MM-003) trial. Investigator Meeting. Paris 9, 10-November-2016
 - **2017** "X Hematology and hemotherapy meeting". Gijon 3, 4-March-2017.
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PUBLICATIONS

- Fernández-Rubio A, López-Cima MF, González-Arriaga P, García-Castro L, Pascual T, Marrón MG, Tardón A. The TP53 Arg72Pro polymorphism and lung cancer risk in a population of Northern Spain. *Lung Cancer*. 2008 Sep; 61 (3) :309-16. Epub 2008 Mar 11.
- Domínguez-García, A., Fernández-Rubio A, López-Cima MF, González-Arriaga P, García-Castro L, Pascual T, Marrón MG, Tardón A. Metabolic gene polymorphisms and lung cancer risk. *Mapfre Medicina* 18(4):292-304 · January 2007
- Avalia-t. Teresa Cerdá Mota. Authors. Aida Rubio A, Puñal Rioboo J, Ruano Ravina A. Diagnosis and treatment of biliary and pancreatic diseases through colonoscopy peroral. Format file: PDF / Adobe Acrobat - Version in HTML. FT 2009/01. Santiago de Compostela, March 2009. Available online: <http://www.galiciasalud.net/Docs/Avalia-t/FT200901ColangioscopiaPeroral.pdf>.
- Avalia-t. Teresa Cerdá Mota. Authors. Aida Rubio A, Ruano Ravina A. Screening for lung cancer. *INF* 2009/01.
- "Anticuerpos monoclonales en tratamiento de mieloma múltiple". Gijón. 14 de Abril de 2016.

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- Fernández-Alvarez, Rubén; Rubio-Castro, Arturo; Sorigue, Marc; Fernández-Rubio, Aida; Glez-García, Esther; Fdez-Alvarez, Carmen; Sancho, J.Manuel. The impact of FDG PET-CT in the staging of follicular lymphoma- a single experience. (Abstract release date: May 19,2016) EHA Learning Center. Fernández R. Jun 9, 2016. 132708. Label abstract 2016.
- "Survey on the perception of Quality of Life of Patients with Osteoarthritis in Spain". Collaboration with OAFI. August 2021.

PERSONAL SKILLS

Communication

- Spanish (native).
- English. High level written and spoken. Intermediate level in E.O.I.(Official School of Languages). Upper Intermediate level (pre-advanced) General English (Netlanguages). Studying advanced level.
- French. Basic level in E.O.I.(Official School of Languages).
- Concise and effective report writer in both English and Spanish.
- Confident public speaker in both English and Spanish.

Teamwork

- Respond to or give leadership when necessary.
- Mindful of team goals endeavoring to influence the group to a successful outcome.
- Retain a consideration for the ability and needs of individual members.
- Good time management acquired from coursework deadlines and previous jobs.

ADDITIONAL INFORMATION

Interests

- Travelled widely across Europe (France, Germany, Belgium and United Kingdom).
- Hobbies include karate, aerobics, animals, music, reading, hiking
- Geographic access
- Informatics, Internet
- Fiji image processing package
- Biological laboratory technics

Personal details

Aida Fernandez Rubio,

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Full clean Spanish driving license since 1999

REFERENCES

- Maria Teresa Fdez. Sanchez: University of Oviedo, mfernandez@uniovi.es; phone: 0034 985104210
- Antonello Novelli Ciotti: University of Oviedo, anovelli@uniovi.es; phone: 0034 985104210 / 0034 985104193
- M^a Esther Gonzalez García: Cabueñes Hospital. Hematology. Phone: 0034 650 915 409