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International Clinical Project Manager/Medical Writer

Experience summary

As clinical project manager, I acquired significant management skills for 8 years in multiple health domain: Oncology, Multiple Sclerosis, Asthma. I also acquired significant skills in managing international CROs and vendors with full oversight on budget and RFP. I reviewed and wrote all clinical documents such as protocol, IB, ICF, patients' card. I was also part of medical review and analyse with the team the patients profiles. I acquired also expertise in pre-clinical development (in vitro and in vivo) as R&D project manager in a pharmaceutical company in Australia. I also developed from my 15 years professional experience in public (French and American) and private research (French and Australian), a significant expertise in in vitro and in vivo analyses with expertise in Diabetes and more significantly in Type 2 Diabetes.

Recently, I have been endorsed for a new challenge as medical writer. My three years' experience lead me so far to revise narratives SOP, prepare and follow the full projects budget for sponsor. I also coordinate and manage narratives documents (safety and efficacy narratives) by supporting outsourced vendor for sponsor.

RESEARCH AND/OR PROFESSIONAL EXPERIENCE

• **Free-lance-Chef de projet clinique/rédactrice médicale**
Mars 2025

• **Institut des MICI/PIBD**
November 2024

--Review and writing of all SOPS for clinical department (regulatory, quality)

• **CRO Excelya-Medical writer coordinator**
July 2021 to September 2024:

-Narratives vendor coordinator/Medical writer coordinator for SANOFI-International trials

- * Project management with CROs international
- * Vendors oversight (budget, meeting): TCS, Cognizant
- * Medical writer coordinator: narrative template, narrative writing quality check, study's timelines
- * Review of narratives document: vendor's quality check of writing versus source documents
- * Review of SOP for medical writing

• **CRO Excelya-Clinical Project Manager**
July 2018 to July 2021:

-Global study manager for SANOFI-International trial in Rare Disease-Pediatric Multiple Sclerosis

- * Project management with CROs international
- * Vendors oversight: Covance, Neurostatus, Esms, PPD
- * Data management oversight (eCRF cleaning, Data Base Lock oversight)
- * Patients profiles-Medical Review

•CRO CLINACT-Senior Clinical Project Manager, International trials

November 2017 to June 2018:

International Clinical Trial-Phase II/III-Oncology, Neurology, Endocrinology

- *Target molecule, Medical Device (class IIa), Medical Connected Device (connected tee-shirt)
- *Clinical data overview (workbook writing) and data management validation
- *Feasibility study in oncology and endocrinology
- *Management of ARC/TEC
- *Protocol writing and SOP documentation writing and quality assessment
- *Submission to Competent and Ethical Committee Authorities (France and international)
- *Clinical Trial budget overview and invoices

•ABScience -Clinical Project Manager, international trials

Dec 2016 to November 2017:

National/International Clinical Trial-Phase II/III-Oncology, Asthma disease

- *Clinical data overview and data management validation
- *CRO coordination in sites management and monitoring activities
- *Protocol amendments/subjects documentation writing and quality assessment
- *Submission to Competent and Ethical Committee Authorities
- *Sites/CRO invoices overview

•ABScience-CRA

July 2016 to December 2016: Monitoring visits, EMA inspection preparation, TMF

•Pharnext-Senior Researcher-Clinical studies

September 2012 to January 2016

- *Biologic Systems Researcher: Molecular network construction in silico for several diseases (Diabetes, Myopathies, Schizophrenia).
- * Off patent drugs repositioned on disease networks, analyzed for toxicity and clinical results and send to experimental biology department.

•Inserm U872, Paris-Senior Researcher-Public Research

November 2009 to September 2012 :

- *Type 2 Diabetes new gene targets analysis: in vitro molecular experiments and cell culture of primary adipocytes (GK rats) and stable cell lines (3T3-L1)
- *In vivo GK rats maintenance^[SEP] Writing referral for animal experimentation to National Ethics Committee^[SEP]

•Inserm U870, Lyon- Senior Researcher-Public Research

February 2008 to October 2009:

- *Project in collaboration with chemists: Monitoring in vivo β cells and T Lymphocytes during pancreatic transplant.
- *Studies in vitro and in vivo of human and mice pancreatic islets labelled with magnetic particles.
- *Test on function and viability of pancreatic islets in vitro followed by MRI and IF studies.
- * In-vivo test of labelled Lt and pancreatic islets transplanted in irradiated NOD mice (sinusoidal injection and renal capsule transplant).
- *MRI of pancreatic islets transplanted NOD mice
- *In-vitro culture of human isolated pancreatic islets and HUVECS to analyse angiogenesis gene pathway following high glucose treatment: QPCR, proteome analysis, angiogenesis assay
- *International articles and reports writing

•ChemGenex – Australia-Pre-Clinical Project Manager

January 2005 to December 2007:

Pharmaceuticals/Metabolic Research Unit-Deakin University-Waurn Ponds, VIC-Australia

- * In vitro and in vivo drugs screening for Type 2 Diabetes
- * In vitro model experiment development of insulin resistance induced by palmitate and $TNF\alpha$ in adipocytes

- *In vivo drugs screening in diabetic Psammomys obesus (P.Obesus) rats Reports and patents writing
- *Collaborative project with Merck-France-Principal investigator-Study of a new drug compound in in-vivo animal models for type 2 diabetes (P .Obesus)
- *Honours student supervisor: Role of Metallothionein in insulin resistance

**•Physiology Unit-Pennington Biomedical Research Center- LA-USA- Post-doctoral Research Fellow
June 2002-December 2004:**

- *In vitro work on fat cell metabolism in human isolated adipocytes of type 2 diabetic and non- diabetic patients: QPCR, Western Blot analyses
- *Method development for primary cell culture from needle adipose tissue biopsy versus liposuction samples in human subjects-collaborative project
- *Setting up a clinical trial in obese diabetic and control patients: protocol lead writing, recruitment lead, in-vitro experimental set up, data and publication lead
- *International articles writing

EDUCATION

March 2025 FORMATIS, Sèvres, France
Medical writer training-clinical reglementary documents (protocol, synopsis, CTD, CSR, CER, patients flyer, PIS, CER)

March 2016 FORMATIS, Sèvres, France
Clinical Research Project Manager training-

2009 DU Experimentation animale-Niveau 1

University Paris VII

1998-2002 Ph D-Physiology and physiopathology of human nutrition A honours with felicitations of board of examiners Multifactorial Diseases Laboratory,

1997-1998 DEA (Honours) in Physiology and Physiopathology in human nutrition- A honours

University of Sciences and Technologies, Lille I

1996-1997 Master's degree in Molecular and Cellular Biochemistry,

1995-1996 Master'sdegree in Physiology and Cellular Biology

GRANTS/AWARDS

1-Cluster Funding-Deakin University-Geelong, Australia- Gene Expression based screening: Application to Insulin Resistance-2007- AUD\$9300

2-Post-doctoral grant-ALFEDIAM-post-doctoral grant-Analysis of energetic metabolism in response to a fast or an increase of food intake in predisposed or resistant individuals to obesity- 2002-6146 euros

3-Award-Nestle Nutrition-France-Study of genetic determinants in familial obesity: involvement of glutamate decarboxylase 2 (GAD2) in food intake behaviour-2002-15,000 euros

4-PhD Grant-Fondation pour la Recherche Medicale (FRM)-PhD grant- Study of genetic determinants of human obesity. Positional cloning of a susceptibility gene for obesity on chromosome 10- 2000-14,635 euros

PATENT

CNRS patent number 02293085.3-Method of diagnosis of obesity- Dubois S, Boutin P, Dina C, Froguel P-february 2003 LABORATORY

PUBLICATIONS

14 international publications (8 first author/1 last author), 1 book chapter, 1 book (Obésité : Aspect Physiopathologique et Stratégie d'Approche Génétique, édition PAF, GmbH&Co, 2012)

Mains Articles :

1- Madec AM, Cassel R, **Dubois S**, Ducreux S, Vial G, Chauvin MA, Mesnier A, Chikh K, Bosco D, Rieusset J, Van Coppenolle F, Thivolet C- Losartan, an angiotensin II type 1 receptor blocker, protects human islets from glucotoxicity through the phospholipase C pathway, **FASEB J.** 2013 Sep 5.

2-Haynes V, Connor T, Vidal H, Tchernof A, **Dubois S**-Metallothionein 2a is increased in subcutaneous adipose tissue of type 2 diabetic patients, **Mol Genet Metab.** 2013 Jan;108(1):90-4

3-**Dubois S**, Madec AM, Mesnier A, Armanet M, Chikh K, Berney T, Thivolet Ch, Glucose inhibits angiogenesis of isolated human pancreatic islets, **J Mol Endocrinol.** 2010 Aug;45(2):99- 105

4-**Dubois SG**, Tchoukalova Y., Heilbronn L., Smith S.R., Albu J.D., Kelley D.E., Smith S.R., Fang X., Ravussin E, Potential role of increased matrix metalloproteinase 2 (MMP2) transcription in impaired adipogenesis in type 2 diabetes mellitus, **Biochemical and Biophysical Research Communications**, Mar 2008, 367(4): 725-8.

5-**Dubois S**, Heilbronn LK, Smith SR, Albu JB, Kelley DE, Ravussin E and the Look AHEAD Adipose Research Group, Decreased expression of adipogenic genes in obese subjects with type 2 diabetes, **Obesity**, 2006, 14:1543-1552.

6-**Dubois S**, Halversen Yan Di C, Gimble JM, Ravussin E, Primary Stromal Cell Culture from Adipose Tissue: From liposuction to Needle Biopsy, **Adipocytes**, 2005, 1(3):139-144.

7- Boutin P, Dina C, Vasseur F, **Dubois S**, Corset L, Seron K, Bekris L, Cabellon J, Neve B, Vasseur Delannoy V, Chikri M, Charles M A, Clement K, Lernmark A, Froguel P. GAD2 on chromosome 10p12 is a candidate gene for human obesity, **Plos Biol.**, 2003, 1: 1-11.

8-Otobe S., Clement K., **Dubois S.**, Lepretre F., Pelloux V, Leibel R., Cheng W., Boutin P., Guy-Grand B., Froguel P.and Vasseur F. Mutation screening and association studies of the human uncoupling protein 3 gene in normoglycemic and diabetic morbidly obese patients. **Diabetes** 1999, 48: 206-208.

9-Hager J., Dina Ch., Francke S., **Dubois S.**, Houari M., Vatin V., Vaillant E., Lorentz N., Basdevant A., Clement K., Guy-Grand B.and Froguel P. A genome-wide scan for human obesity genes reveals a major susceptibility locus on chromosome 10, **Nature Gen.**, 1998 20: 304-308.