Curriculum Vitae

Personal information

Name:	Carremans	Place of birth:	Hasselt
Surname:	Claudia	Date of birth:	19 April 1982
Address:	Terbiest 140		
	3800 Sint-Truiden	Nationality:	Belgian
Mobile:	+32 (0)479 38 82 75	Civil Status:	Married
Email:	claudia@clinicalconsulting.be		

Work experience

08/2024	Freelance 'CC Clinical Consulting'
05/2016 – Current	Allucent Belgium - CRO (*merge between 'Pharm-Olam International' and 'Cato SMS'*) Clinical Research Associate 05/2016 – 03/2018: CRA I 03/2018 – 03/2021: CRA II 03/2021 – 06/2023: CRA III – Regulatory specialist 06/2023 – current: Senior CRA – Regulatory specialist
06/2015 – 05/2016	Infarama bvba (Consultancy) *Specification*: Pharmacovigilance - Materiovigilance
2011 - 05/2015	Regulatory Affairs Terumo Europe N.V. Interleuvenlaan 40, 3000 Leuven *Specification*: Medical Devices - Interventional systems
2007 - 2011	Clinical Trial Assistant Pneumology (project coordination – management) Katholieke Universiteit Leuven Herestraat 49, 3000 Leuven *Specification*: COPD ('Chronic Obstructive Pulmonary Disease')

Studies

2010	Pharmaceutical assistant, not finalized (start exams + training at Pharmacy)
2005 – 2007	'Katholieke Universiteit Leuven', Leuven Study: Master Biomedical Science
2004 – 2005	'Vrije Universiteit Brussel' (VUB), Brussel Study: 2de candidature Biomedical Science
2001 – 2004	'Katholieke Hogeschool Limburg', Diepenbeek Study: Medical Laboratory Technology
1999 – 2001	'Vrij Technisch Instituut', Diest Study: Technical Sciences
1998 – 1999	'Voorzienigheid', Diest Study: Sciences - Mathematics
1994 – 1998	'Instituut Onbevlekt Hart van Maria', Lummen Study: Modern Languages – Economy

Traineeship:

2006 – 2007	Training 'Biomedical Science' Janssen Pharmaceutica, Turnhoutseweg 30, B-2340 Beerse

Division: Oncology
Project: Drug Discovery & Development

2005 'VZW Maria Ziekenhuis Noord-Limburg Campus Heilig Hart' (job student)
Stationsstraat 76, 3910 Neerpelt
Divisions: Hematology, Microbiology, Biochemical

2004 Training 'Medical Laboratory Technology'
'Maria Middelares Ziekenhuis Noord-Limburg'
Kliniekstraat 2, 3920 Lommel
Divisions: Hematology, Microbiology, Biochemical en Anatomy/Pathology

2004 'Maria Middelares Ziekenhuis Noord-Limburg' (job student)
Kliniekstraat 2, 3920 Lommel
Divisions: Hematology, Microbiology, Biochemical

Experiences as Clinical research Associate (current)

- Study start-up (Evaluation visits, Initiation visits, site management, monitoring visits, close-out visits, motivational visits,...)
- Site contract negotiations.
- Preparation, compilation, submission and maintenance of regulatory documentation required by CA/CEC/LEC and Ethics committees for clinical trials. Maintenance in preparation of the answers to the comments coming from CA/CEC/LEC. (including Annual Reporting)
- Performing initiation, Monitoring and Closure Visits at Investigator Sites according to project schedule. Adheres to project guidelines and SOPs for monitoring requirements. Preparation site visit reports and telephone contact reports.
- Monitor activities at clinical study sites to assure adherence to protocol, Monitoring Plan, ICH, GCP, SOPs, and applicable regulations and guidelines.
- In case required, participate in the start-up process including preparing Informed Consent forms, developing study documents, EC / CA submissions, and / or site contract management
- Conducts co-monitoring as needed.
- Liaises with project team members and Sponsor to track study progress and milestones.
- Resolving site issues, including site recruitment challenges and determines status for IP shipment.
- Translation, coordination of translations or the review of completed translations of critical documents.
- Tracks and supervises collection of ongoing study data for purpose of regular project status reporting.
- Assists the Project Manager (PM), Clinical Team Leader and/or Lead CRA (CTL/LCRA) with generation of study specific forms for completion by CRA and Investigators and follow up with the teams to ensure timely completion and submission.
- Organizes processes for interim and final payments to Investigators, including preliminary calculations, review and approval from Project Management, liaison with accountant, logging trial expenditure, receipts, invoices, and income.
- Assessment visits
- Supports site staff in preparation for study related site audits and inspections.
- Reports Quality Issues and supports the root cause analysis, writing of and resolution of the Corrective and Preventative Actions.

- **Clinical Trial Experience:**
    - Cardiology
        - Cardiomyopathy - Phase I
        - Hypercholesterolemia - Phase III
    - Gastroenterology
        - Ulcerative Colitis - Phase II
    - Hematology-Oncology
        - Hematological Malignancies - Phase III
    - Infectious Disease
        - Viral – Influenza - Phase II
    - Neurology
        - Back Pain - Phase II (main study + follow-up)

        - Genetic disorder
            - Duchenne Muscular Dystrophy (DMD) – Phase IV
        - Oncology
            - Brain - Phase III
            - Endometrial Cancer - Phase III
            - Solid Tumors - Phase II
            - Pancreatic Ductal Adenocarcinoma (PDAC) – Phase I-II
        - Pulmonology
            - Obstructive Pulmonary Disease, Chronic - Phase Observational
        - Endocrinolgy
            - Acromegaly – Phase III
- eTMF:
    - TrialInteractive
    - Veeva Vault
    - iMedidata CTMS
- EDC:
    - eCaselink
    - iMedidata Rave
    - Advantage eClinical
    - Zelta
- IXRS:
    - Endpoint
    - Vennlife
    - 4G Clinical
- Other:
    - MLM online
    - QMS median
    - AG Mednet
    - SmartSheet
    - CESP
    - World Care Clinical
    - Median

Experiences as Pharmacovigilance officer (2015 – 2016)

- Activities related to pharmacovigilance - materiovigilance
- Application Distribution License Medical Devices (class I, IIa and IIb)
- Notification Medical Devices Class I
- Notification Local Contact Person Pharmacovigilance
- Contacts with customers (national and international)
- Review and writing internal/external procedures (SOPs and WI)
- Writing ‘Periodic Safety Update Report’ (PSUR)
- Preparation ‘Safety Data Exchange Agreement’
- Participation customers audit
- 24/7 call service
- EudraVigilance

Experiences as Regulatory Affairs officer (2011 – 2015)

- 4 years’ experience in Regulatory Affairs
- Preparing/Review Product Registration (Technical) Files including all required additional documents/statements/certificates for countries worldwide + submission + follow-up approvals.
- Preparation/Review “Instructions for use” and Labeling of the medical device
- Preparation Literature Search Report

- Application and follow-up requests “Free Sales Certificates” at Belgian MOH (FAGG), Chamber of Commerce (VOKA)
- Notarizations and legalizations at Ministry of Foreign Affairs and Embassy
- International communication related to registrations, additional questions,…
- Administer procedures, contracts,…
- Knowledge of GMP – GCP – GDP
- Knowledge of Regulations and Standards related to Medical Devices
- Knowledge of SOP’s
- General knowledge in Pharmacovigilance
- General knowledge DCP/RMP

Experiences during my job as Clinical Trial Assistant (2007 – 2011)

- Distribution and follow-up of the study protocol
- Trial management, planning and coordination
- Trial set-up and execution
- Budget management
- Setting up required documents regarding approval of Ethical Committee (combined with FDA/FAGG, EudraCT, ClinicalTrials.gov), amendments and application at SMB.
- The development of the informed consent, CRF, and questionnaires.
- Patient recruitment, randomization, and retention
- Blood collection
- Measures progress against goals to achieve clinical research targets.
- Verify the study data
- Oral presentations
- Set up and coordinate meetings, patients and project planning and including work planning colleagues.
- Data management
- Follow up on timelines and the yearly reporting
- Time registration for the different staff on the project

Extra training

Annually	The Principles of the ICH GCP – Refresh training
2010	Certificate: "Project management"
2007 – 2009	Centrum voor Levende Talen (Leuven) Certificate: English (level 2 en 3)
2007 – 2008	Vlaamse Vereniging voor Respiratoire Gezondheidszorg en Tuberculosebestrijding Study: Tabacology Certificate: Tabacologe
2007	Katholieke Universiteit Leuven Certificate: Microsoft Access 2002
03/2004	Katholieke Hogeschool Limburg (Diepenbeek) Certificate: Stem cells: from laboratory study to clinical objectives.
03/2003	Katholieke Hogeschool Limburg (Diepenbeek) Certificate: New trend in the microbiologic research of respiratory samples.
12/2003	Virga Jesseziekenhuis (Hasselt) Certificate: “Quality control in a clinical lab: from the standard to the routine”.

Language knowledge

- Dutch: native
- English
- French: basic

Computer knowledge

- MS Office (Word, Excel, Access, PowerPoint, Outlook, OneNote)
- OneDrive
- (Drop)Box
- Teams, Zoom,…
- Adobe Acrobat Pro X / DC
- Adobe InDesign CS6
- Internet (Edge, Chrome,…)
- SAP

Personality

- Team player
- Critical
- Flexible, spontaneous, social
- Strong communicative ability
- Focused and strongly result driven

Publications

- Alveolar and bronchial exhaled nitric oxide in chronic obstructive pulmonary disease.
  Lehouck A, **Carremans C**, De Bent K, Decramer M, Janssens W.
  Respir Med. 2010 Jan 22.
- Vitamin D deficiency is highly prevalent in COPD and correlates with variants in the vitamin D-binding gene.
  Janssens W, Bouillon R, Claes B, **Carremans C**, Lehouck A, Buysschaert I, Coolen J, Mathieu C, Decramer M, Lambrechts D.
  Thorax. 2010 Mar;65(3):215-20. Epub 2009 Dec 8.
- Vitamin D beyond bones in chronic obstructive pulmonary disease: time to act.
  Janssens W, Lehouck A, **Carremans C**, Bouillon R, Mathieu C, Decramer M.
  Am J Respir Crit Care Med. 2009 Apr 15;179(8):630-6.