Curriculum Vitae
Owner and Manager of Ad Hoc Clinical
Consultant : Clinical Research Specialist

ID:	:	NANCY COTTIGNY
NATIONALITY	:	BELGIAN
YEAR OF BIRTH	:	1971
GENDER	:	FEMALE
BASED IN	:	IEPER, BELGIUM

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CURRENT ROLE

Company	:	Adhoc Clinical (since April 2009)
Activity	:	**Clinical Research Consultant**
Function	:	Clinical Research Consultant for various clients Supervise and coach a team of CRA's (in France and Belgium)

Services offered

PROJECT MANAGER : PARTICIPATE IN PROJECT PLANNING BUDGETING AND EXPENSE, ESTABLISH AND GUARD STUDY TIME-LINES, WRITE PROTOCOL SPECIFIC SOPS; ANALYSE IDENTIFY AND SOLVE ISSUES RELATED TO THE PROJECT, IMPLEMENT RESOLUTIONS, ASSIGN AND SUPERVISE FIELD MONITORS, COMMUNICATE TO SPONSOR ON STUDY PROGRESS, PLAN AND CREATE PRESENTATIONS OF CLINICAL RESEARCH STUDY INFORMATION

START UP SPECIALIST : EC SUBMISSIONS, MOH SUBMISSIONS, SITE CONTRACT MANAGEMENT, SITE SELECTION AND QUALIFICATION VISITS, SIV VISITS

MONITOR : SITE SELECTION AND QUALIFICATION VISITS, SIV VISITS REMOTE AND ONSITE MONITORING, SITE MANAGEMENT, PRE AUDIT VISITS, CLOSE OUT VISITS...

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Studies Involved with

OPEN LABEL STUDIES : SINCE JUN1997
PHASE I: SINCE NOV 2001
PHASE II: SINCE OCT1999
PHASE III: SINCE SEP1997
PHASE IV: SINCE JUN1997
SURVEYS: SINCE JUL 2002
OBSERVATIONAL STUDIES : SINCE JUN1997
IN VITRO DIAGNOSTICS: SINCE APRIL 2009
BIOEQUIVALENCE STUDIES: SEPTEMBER 2010

EXPERTISE PER THERAPEUTIC AREA

Phase I: oncology- respiratory diseases- urology- dermatology
Phase II: oncology – pain- dermatology- trauma
Phase III: psychiatry- immunology- allergy- migraine- multiple sclerosis- oncology
Phase IV: HIV – migraine- diabetes- oncology- studies with genetically modified organisms
PASS studies: various studies
Non interventional studies: psychiatry- HIV-paediatric studies
Bioequivalence studies: oncology

In vitro Diagnostica: performance evaluation studies, SOP writing, monitoring, rules EU regulations

WORKING AREA

France, Belgium, Netherlands

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TASKS and RESPONSABILITIES

- Ensure efficient and effective execution of all Phase I-IV clinical trials
- Ensure efficient and effective execution of clinical investigations (devices)
- Build, coach and mentor team of CRA's and ensure deliverables are met
- Permanent monitoring of Clinical Trial regulations and adapt internal SOP's accordingly
- Ensure CRA's of my team are adequately trained
- Manage scope of work and budget revisions+ change resource allocations where appropriate
- Ensure appropriate, comprehensive and professional communications both to client and sites
- Provide input into design and implementation of clinical protocols, quality assurance, data collection systems and final reports
- Develop own + review clients contracts, quotations and delegation of tasks and responsibilities
- SOP review and writing (clinical trials and clinical investigations)
- Creation of study documents (CRF, Patient Information Sheet and Informed Consent Form, diary)
- Organise and negotiate contracts with hospitals and investigators (private and public)
- Submission and Follow up of the Clinical Trial Applications to the Competent Authority (EU)
- Submit protocol to obtain approval from Central and Local Ethical Committees / privacy committee/ … (Fr-Be-Nl)
- Review and adapt essential study documents to local standards (France-Belgium-Netherlands)
- Organise study Feasibility and site selection
- Initiation visits
- Remote monitoring
- On site Monitoring visits
- Closure Visits
- Pre and post audit visits
- AE and SAE reporting and Follow up
- Query handling
- Drug accountability
- Laboratory visits (blinded or unblinded)
- Creation of organisational documents (tracking charts…)
- Creation of Newsletters
- Project Coordination for multicentric trials
- Co-monitoring visits
- Overall project management
- Track progress of study milestones and address problems as necessary
- Active control of timing and deliverables and budget
- Select and supervise partner service providers

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PREVIOUS FUNCTIONS WITHIN THE ARENA OF CLINICAL RESEARCH

Company	:	IATEC France (formelly known as C.R.A.) CRO
Activity	:	Service provider to pharmaceutical industry organising and validating clinical studies on human beings
Period	:	January 2006- November 2008
Function	:	**Country Manager for team of 10 (CRA's and PL)**
Reporting to	:	CEO

Company	:	Clinical Research Assistance Belgium (C.R.A.) / CRO
Activity	:	Service provider to pharmaceutical industry organising and validating clinical studies on human beings
Period	:	November 2000- December 2005
Function	:	**Clinical Operations Leader C.R.A. Belgium** Member of management team C.R.A. Belgium
Reporting to	:	General Manager C.R.A Belgium

Company	:	Zeneca nv, Destelbergen (Belgium) / pharmaceutical industry
Activity	:	research, production and sales of pharmaceutical products and apparatus
Period	:	June 1997 - October 2000
Function	:	**Clinical Research Associate / Project Leader**
Reporting to	:	International Project Leader / Line Manager

EDUCATION

MASTER	:	Gestion et management stratégique, general management level (Master in strategy and organisation)
School	:	IFG Lille (Institut Français de Gestion) -France
Period	:	2005-2006

BACHELOR	:	Physiotherapy A1 (Bachelors degree)
School	:	Simon Steven Institute Bruges- Belgium
Period	:	1989-1992

COMPUTER KNOWLEDGE

Daily use of MS Office: Word/ Excel/ PowerPoint / Publisher/ MS Projects

LANGUAGES

Flemish /French/ English	:	trilingual
Spanish	:	conversation level
German	:	basic

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SKILLS

- Global approach
- Good organiser
- Communicative
- Creating of long term relationship
- Problem solver
- Able to prioritise
- Sense of humour

PERSONALITY according to Briggs- Myers type indicator

ENTJ: extraverted thinker with intuition
Described by Briggs- Myers as logical, structured, objective and decisive about what they view as conceptually valid. Enjoys working with others especially when they can take charge and add value to a strategic plan

MEMBERSHIPS

DIA member
Member of Be CRO (Belgian CRO organisation)
Member of EFGCP (European Forum for Good clinical Practice)
Member of Club Phase I
Active member of EUCROF Working group on medical devices and IVD's
Teacher at ILIS France : teaching Clinical Research Modules to Bachelor and Masters Biomedical Engeneers /CRA's

WHEN I HAVE SOME TIME FOR MYSELF

Sailing / skying / gardening / reading children stories in foreign languages/ occasionally read serious novels as well

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Appendix 1: Training Record

A/ Therapeutic area training

- prostate cancer (Zeneca Belgium- 1997 – 3 days)
- breast cancer (Zeneca Belgium -1998- 2 days)
- hormonotherapy (Zeneca Belgium -1997-2 days)
- migraine (Almirall Belgium- 2000- 1 days)
- cardiovascular physiology and pharmacology (Zeneca Belgium- 1999-2 days)
- hypertension: pathology and treatment (Zeneca Belgium-199—2 days)
  basic principles nephrology
- asthma and COPD: pathology and treatment (AstraZeneca Be -2000 -2 days)
- soft tissue sarcoma (Client- May 2011- monitor meeting)
- effects of blood loss (Client –March 2012—webex training)
- Resist 1.1 (webex training client, April 2012)
- Inflamatory bowel disease :crohn and Ulcerative Colits:(webex training client, April 2013)

B/ Clinical research training

- clinical trial procedure course (Zeneca UK- 1998- 5 days)
- monitoring workshops various clients
- drug registration procedures in Belgium and in Europe (Zeneca Be- 1999- 1day)
- Update EU directive France, (Euroforum, Paris 2006, 2 days)
- Regulation of clinical trials in France : update for advanced users (Development Institute International, Lille, 1 day, 22 May 2007)
- Comparison regulations research on devices +diagnostics versus drugs (private consultant , Gent April 2009)
- International Requirements, rules and regulations of Non interventional trials (Mapi- Paris- 2011)
- Permanent SOP training and GCP refrechers various clients (2009-2012)
- Use of ECRF (inform 4.6 - oracle ... last training done in April 12)

C/ General training

- training Project Management (CRA International, Netherlands, 2002)
- Use of software package MS project (Consultant Ghent, 2002, 3 days)
- Financial Management (chambre de commerce Lille, 2002, 5 days)
- Giving Feed-back to staff (Hipepe Belgium, 2004,1 day)
- Mastering Negotiations (Amelior Belgium, 2004, 5 days)
- Comment gagner de nouveau clients (IFG France, 2005, 2days)
- Mission and vision exercise (Consultant Netherlands, 2005, 2 days)
- Business Contracts with clients, investigators-CRO's- SMO's in France (Euroforum, Paris, 2006, 1 day)
- ICG : Cycle de management supperieure : Master in Strategy and Organisation (Institut Français de Gestion, March 2005 to December 2006)
- Use of RACI in contract and project management (Motion 5, April 2007, Netherlands, 2 days)
- Human Resource Management (IFG,Paris, 3days, November 2007)
- Delegation de pouvoir (Development Institute International, Paris, 24th of June 2008)
- TOPRA symposium Oct 2012 + Medical Device Symposium
- Medical Device Directives+ CE marking and technical File (Jan 13)

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