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

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

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CURRENT ROLE

Company	:	Ad Hoc Clinical (since April 2009)
Activity	:	Founder and **Managing Director**, **Clinical Research Consultant** of Ad Hoc Clinical
Function	:	Clinical Research Consultant for various clients Supervise and coach a team of CRA's (Own team + freelancers all over Europe)

RESEARCH INVOLVED IN

OPEN LABEL TRIALS : SINCE JUN 1997
FIRST IN MAN STUDIES: SINCE 2009
PHASE I: SINCE NOV 2001
PHASE II: SINCE OCT 1999
PHASE III: SINCE SEP 1997
PHASE IV: SINCE JUN 1997
SURVEYS: SINCE JUL 2002
OBSERVATIONAL STUDIES : SINCE JUN 1997
MEDICAL DEVICE INVESTIGATIONS: SINCE 2010
IN VITRO DIAGNOSTICS: SINCE APR 2009
BIOEQUIVALENCE STUDIES: SEP 2010

EXPERTISE PER THERAPEUTIC AREA

Phase I: oncology - respiratory diseases – urology - dermatology
Phase II: oncology – pain - dermatology - traumatology – respiratory diseases
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 drug studies: psychiatry - HIV-paediatric studies
Bioequivalence studies: oncology

Medical Device studies: pre and post CE label clinical investigations, submission to EC/CA
In vitro Diagnostica: performance evaluations pre CE label, SOP writing, submission to EC/CA, training
*Detailed list available

SERVICES PROVIDED

PROJECT MANAGEMENT :

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, PARTICIPATE TO CLINICAL TRIAL REPORT WRITING

START UP ACTIVITIES :

EC SUBMISSIONS, MOH SUBMISSIONS, DATA PROTECTION NOTIFICATIONS, SITE CONTRACT MANAGEMENT, SITE SELECTION AND QUALIFICATION VISITS, SIV VISITS

MONITORING :

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

TRAINING:

MAKE TRAINING PLAN FOR CLINICAL RESEARCH PROFESSIONALS, PROVIDE AND ORGANISE TRAINING FOR OWN TEAM OR CLIENT TEAMS, ACT AS AN ACCOMPANYING MONITOR , COACH JUNIOR AND SENIOR STAFF

SOP WRITING:

MAKE AND/OR REVIEW SOP'S FOR CLINICAL TRIAL ORGANISATIONS (CRO'S -HOSPITALS-SPONSORS) FOR TRIALS ON DRUGS OR IN VITRO DIAGNOSTICS

GDPR:

CONSULTING AND TRAINING FOR CLINICAL TRAIL RESEARCH PROFFESIONALS

WORKING AREA

Europe

TASKS and RESPONSABILITIES

- Submit for regulatory approval for studies with drugs (pre and post MA , interventional, observational, registries, PASS studies, FIM studies, ...) Submit protocol to obtain approval from Central and Local Ethical Committees
- Submit for regulatory approval for studies with (IVD) MD (pre and post CE label , interventional, non interventional studies),
- 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 / Clinical Investigations/ Clinical Evaluations regulations and adapt internal SOP's accordingly
- Ensure CRA's team in Ad Hoc Clinical 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 performance evaluations)
- Creation of study documents (CRF, Patient Information Sheet and Informed Consent Form, diary, monitor plan, project management plan)
- Organise and negotiate contracts with hospitals and investigators (private and public)
- Submission and Follow up of the Clinical Trial Applications to the Competent Authority (Europe)
- Review and adapt essential study documents to local standards (Europe)
- 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
- Pharmacy visits (blinded or unblinded)
- Creation of organisational documents (tracking charts…)
- Creation of Newsletters
- EU Project Coordination for multicentric trials
- Co-monitoring visits
- Track progress of study milestones and address problems as necessary
- Active control of timing and deliverables and budget
- Select and supervise partner service providers
- Study coordination Europe for World Wide Studies
- Overall project management

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

TRAINING

CERTIFICATE	:	Data Protection Officer
School	:	Data Protection Insitute - Belgium
Period	:	November 2017
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

SKILLS

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

TEACHING AND PRESENTATIONS

- Former Teacher at Insititut lillois d'ingénierie de la Santeé (ILIS France)
    - Teaching Clinical Research Modules to Bachelor and Masters in training to become Biomedical Engineers /CRA's
- Speaker for EUCROF : Webex presentation on IVD current and future rules and regulations Nov 14
- Trainer for ECCRT (European Centre for Clinical Research Training) on GDPR Clinical Trials Professionals

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

Member of Be CRO (Belgian CRO organisation)
Member of EFGCP (European Forum for Good Clinical Practice)
Member of AFPT_ Club Phase I (Fr) / Bapu (Be)
Active member of EUCROF Working group on medical devices and IVD's
Member of Healixia (Belgian Regulatory Affairs Society)

WHEN I HAVE SOME TIME FOR MYSELF

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

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 (Zeneca Belgium-199—2 days)
- 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 Colitis:(webex training client, April 2013)

B/ Clinical research training ICH GCP certificate: valid until Feb 2021

- 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)
- TOPRA symposium Oct 2012 + Medical Device Symposium
- Medical Device Directives+ CE marking and technical File (Fakkel, Jan 13)
- Focus on IVD clinical evaluations and prepare for upcoming EU regulation (Fakkel, March 2014)
- TOPRA meeting on planned EU clinical trial regulations (Sept 14)
- Master Class Cellular Therapy (Biowin – March 2015)
- Bapu Symposium Safety and Regulation in Early Drug Developent (BAPU, Dec 16)
- Permanent SOP training and GCP refrechers various clients (2009-today)
- Use of ECRF (inform 4.6 – oracle- medidata Rave … last training done in Dec 16)
- Addendum to ICH E6 (R2) - The Impact on your Daily Research Reality' (Trium, 8 Dec 17)
- GCP compliance on TMF, draft EMA guideline EMA/15975/2016 (Brookwood, May 17)
- GDPR essentials (iHasco 25 Jun 18)
- GCP compliance training for HCPs V2.0 (Febr 2019)
- Science, Technology and Regulations (Amsterdam Feb 2020)

C/ Non research related 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)
- Data Protection Officer (Data Protection Institute, November 2017)
- General Data Protection Regulation (Delsols avocats, Paris, 22nd of June 2018)
- Risk-based and Remote monitoring (Webinar July19)

AD HOC CLINICAL PERSONAL DATA POLICY

Conditions of use:
The collection and processing of personal data of citizens of the European Union is regulated by the European Data Protection Directive (95/46/EC), updated by the European regulation 2016/679 and national laws. Such laws, directives and regulations generally prohibit the transfer of the personal data of European citizens unless consent to such a transfer has been obtained.

Ad Hoc Clinical is committed to respecting the privacy of its staff and has obtained written consent to transfer the personal date in present CV for the intended use described below.

The receiver must treat this personal and confidential information received in any form, as strictly confidential and fully comply with all protection and security measures detailed in the 2016/679 EU Global Data Protection Regulation. this regulation also applies to receivers not located in the European Union.

The receiver of this CV cannot alter, communicate, transmit or disclose the personal and confidential information in whole or in part, directly or indirectly, to third parties, without prior written consent of Ad Hoc Clinical BVBA.

Ad Hoc Clinical authorizes the receiver to transmit this personal data to the employees of the receiver, who are required to be informed of the personal and confidential information and to any authorized third parties such as national or international competent authorities providing that they are bound by similar confidentiality and data protection obligations.

The receiver is liable in case such measures are not used. The burden of proof lies with the receiver.

Intended use:
The receiver may use the provided personal and confidential information only for following purposes:

- as part of a vendor selection process to verify the competences of an individual Ad Hoc Clinical team member who has been put forward to a buyer for a specific mission to be executed by Ad Hoc Clinical staff
- for filing in purposes
    - proof of qualification for tasks executed in the context of a mission
    - study documentation in a study specific trial master file or other related documentation
    - meeting registration purposes
    - training registration purposes
    - other administrative purposes

The receiver may only store this personal and confidential information for the following duration:

- 2 months after receipt: for vendor selection purposes
- 25 years after receipt: for study documentation purposes (as per current ICH GCP requirement as detailed in E6R2)

As per European regulation 2016/679, the owner of this personal data (concerned individual) must be allowed to access his/her personal data at any time and has the right to correct any inaccurate or incomplete information. The concerned individual has also the right to request erasure of the data unless the data must be retained to comply to other applicable guidelines laws or regulations (in example: ICH GCP).