Coquelle Consulting

Curriculum Vitae
Thomas Coquelle

PROFILE

With more than 23 years' experience in Clinical Research, I have now started my own company supporting clinical operations and development. I am a champion in the end to end process of trial planning and conduct on the global level. The last 2-3 years I have been in the innovative space for transforming the conventional approach of clinical trials to implement new technologies hereunder working with decentralized clinical trials. During my career I have had multiple positions within project and trial management, focused on actual trial management and process optimization such as Risk-Based Monitoring and other key clinical trial processes in the sponsor organization. I have successfully managed and lead multi-disciplinary and international teams for multi-national trials in several therapeutic areas in different phases across the globe.

BACKGROUND

Coquelle Consulting (2023-)
CEO and founder

L E O (2017-2023)
Principal R&D Project Manager,
Clinical Project Manager

TFS (2016-2017)
Senior Project Manager

Lundbeck (2008-2015)
Principal Clinical Study Manager,
Clinical Operations Manager,
consultant

PAREXEL (2006-2008)
Clinical Lead, Senior CRA

Pfizer (2002-2005)
Clinical Study Manager, CRA

KEY COMPETENCIES

- Champion in **innovative solutions** such as online recruitment, eConsent solutions, or decentralized elements that allow to reach remote populations via telemedicine and Bring Your Own Device options.
- Extensive experience in all aspects of **clinical project management** of phase 2-4 multinational clinical trials.
- Extensive experience in all aspects of **clinical project management** of phase 2-4 multinational clinical trials.
- **Goal-oriented**, dynamic, and decision-driven and is not afraid to questioning the status quo when I can see the potential for improvement.
- Leadership of **cross-functional and multicultural teams** both F2F and from a distance.
- Analytical, pro-active and collaborative **mindset**
- **Motivation** of team members by inclusion in decision process, acknowledgement and using feedback.
- Long-term experience with working with multiple nationalities

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PROFESSIONAL EXPERIENCE & ACHIEVEMENTS

Coquelle Consulting

April 2023- **CEO and founder**

Consulting in Innovative solutions, education and training, project management and trial management Clinical Project Management and Trial Management – see www.coquelle-consulting.com

L E O

Apr 2020- April 2023 Principal **R&D Project Manager / Revolutionize Clinical Trials**

Overall responsible for pilot trial with 100% decentralization in LEO Pharma using innovative technology. Leading innovative project team including internal and external stakeholders. Leading internal project team including QA and Legal. External stakeholder management including leading interactions and advice meetings with authority regarding decentralized clinical trials. Experienced presenter and teacher at multiple seminars/conferences representing LEO Pharma.

Apr 2017- Mar 2020 Principal **Clinical Project Manager**

Trial Management - overall accountable for trial team deliveries

- Responsible for start-up in phase 3 trial in Atopic Dermatitis.
- Lead CPM for start-up of phase 2b clinical trial program for Chronic Hand Eczema.
- Supporting CPM for Study Closure of Topical treatment in a phase 3 Psoriasis treatment.
- Responsible and key driver for implementing processes for Protocol Deviation processes
- Champion CPM for implementing Risk Based Monitoring, and Veeva CTMS and multiple other clinical trial processes in LEO Pharma.

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Jan 2016- Mar 2017 **Senior Project Manager**

CRO project manager for execution of two global phase IV studies. COPD study in 23 countries and 219 sites and PAH study in 7 countries and 40 sites. Part of the International Project Delivery organization and had the overall responsibility for managing international projects, according to company policies, timelines, SOPs and regulatory requirements.

- Leading multinational "Lead CRA" teams (2 Lead CRAs in PAH study and 6 Lead CRAs in COPD) study.
- Involved in process optimization for Risk Based Monitoring in TFS and had several speaks at International congresses on this topic during this time (see "presentation")

Jan 2014- Dec 2015 **Principal Clinical Study Manager**

Principal Clinical Study Manager planning and execution of phase 4 study in Alcohol Dependence, 5 countries in Europe (Germany; France, Spain, Italy and UK), 70 sites in primary care. Supporting Study Manager in phase 2 ADHD study (US:

- Lead and coordinate core study teams in writing two clinical study protocols (ADHD before time and Alcohol Dependence on time
- Leading core study team and CRO for successful implementation of new process for risk based monitoring using the Alcohol Dependence study as pilot study.
- Leading vendor selection process and contract negotiation of new CRO, Scales Vendor and Central Lab.
- Successful management of study budget of more than 9 mio Euro.

Jun 2010- Dec 2013 **Clinical Operations Manager**

Key member of International Study Manager team for Stroke program of two phase 3 studies. (29 countries, 195 sites) regional responsibility for Europe, South America and North America.

- Acting as subgroup leader for Europe implementing action plans and demonstrated increasing recruitment in Europe.
- Leading and revitalizing collaboration with Stroke Key Opinion Leaders in Europe.
- Leading core study team, to implement new procedure for Protocol Deviations and handling of 24 month Post-follow up period.
- Main driver for creating new interactive concept for 3 global investigator meetings and main responsible for big international meeting in Barcelona Feb-2013.
- Conducted Sponsor site visits and Investigator meetings in Austria, Brazil, Estonia, France, Poland, Spain, Germany, UK and US.

- Main driver for onboarding new vendor for Recruitment Enhancement in Europe.

Overall International Study Manager planning and execution of phase 3 study in Alcohol Dependence (7 countries, 63 sites). **References:** Lisbeth Hjorth Christensen (lshc@novonordisk.com), Senior GCP advisor, Novo Nordisk

- Coordinator of a Clinical Working Group an element of regulatory framework planning for regulatory submission of MAA.
- Leading core study team and CRO in achieving database lock according to timelines in study with a huge data cleaning backlog. This study was the last phase 3 study and a prerequisite for meeting timelines for the MAA submission.

ArrayDiagnostica insourced to Lundbeck

Sep 2008 - Jun 2010 **International Study Manager (Consultant)**

Responsible International Study Manager planning and conduct of phase 3 study Major Depression Disorder – 13 countries – 80 sites and phase 2 study Schizophrenia 8 countries/30 sites. Leader of SOP writing group.

- Leader of Study Management Team from relevant departments in Lundbeck HQ. Collaboration with CRO and Lundbeck Affiliates.
- Co-leading and executing premature closure of MDD study.
- Sponsor site visits in Poland, France, Thailand, Hong Kong and Taiwain.
- Leading SOP writing group consisting of cross-function.

PAREXEL

Jul 2006 - Aug 2008 **Clinical Lead**

Operational Team Leader for Clinical Team for 4 multinational studies (breast cancer- phase 2 , ovarian cancer phase 2, COPD phase 2 and Osteoporosis phase 3b). Part of CRO Study Management Team together with Project Manager and other functional leads in Parexel. Primary clinical contact to sponsor. Planning and conduct of Investigator/CRA meetings Accompanied Site Visits.

Jan 2006-Jun 2006 **Senior Clinical Research Associate**

Site Manager for 4 studies in Denmark – hypertension, phase 4 startup, breast cancer phase 4 startup, Percutaneous Coronary Intervention/AMI phase 3a, monitoring/ termination. ICF translation, EC submission, Investigator contract negotiations. Accompanied Site Visits support junior CRAs

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Jan 2004 - Dec 2005 **Clinical Study Manager**

National Study Manager for two Post Marketing Surveillance Studies – Growth Hormone (Genotropin) Databases. Close collaboration with marketing and global HQ. Responsible for training and supporting CRAs.

Oct 2002 - Dec 2003 **Clinical Research Associate**

CRA part of large CRA team responsible for monitoring ASCOT trial (Hypertension and Hypercholestolaemia, phase 4, GPs)

Omnicare Clinical Research

Apr 2001 - Sep 2002- **Clinical Research Associate**

Field based CRO-CRA responsible for Schizophrenia study, phase 3b monitoring and ARDS/ICU phase 3a – startup.

Nomeco

Jan 2001 - Mar 2001 **QA Pharmacist**

Responsible for Quality Assurance System in Nomeco, Denmark's largest medicine distributor (Maternity leave).

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EJJ A/S

Aug 2000 - Dec 2000 **Building Site foreman**

Supporting family business Building Contractor during job search

PRESENTATIONS/ EDUCATION / DIPLOMAS

- **Multiple presentations regarding Innovative Solutions in Clinical Trials**

- **CASE PRESENTATION:** RBM Study Results for Primary Care Study at RBM Europe, March 14-15, 2016, Barcelona, Spain, a CBI event "
- **PRESENTATION: "Principles of safety in phase II studies"**. at Medicademy Pharmacovigilance Module 5: Preclinical and clinical aspects of pharmacovigilance, scheduled February 23-24, 2016, Copenhagen, Denmark
- **Presentation: "Planning and experiences with Risk-Based Monitoring"** at members meeting for Danish Society for Good Clinical Practice, 25 January 2016, Denmark
- **PRESENTATION: How a sponsor can implement Risk Based Monitoring in phase 2-4 studies.** at the 4th Clinical Trial Innovation Programme, 22-23 October 2015, Frankfurt, Germany at the 4th Clinical Trial Innovation Programme 2015, 22-23th October 2015, Frankfurt, Germany
- **"A focus on how Lundbeck has implemented Risk Based Monitoring in late-phase studies"** at Outsourcing in Clinical Trials Nordics 2015, 9-10 September 2015, Copenhagen, Denmark
- "**Panel Discussion; outlining solutions to achieving patient enrolment targets within and outside the Nordics**" at Outsourcing in Clinical Trials Nordics 2015, 9-10 September, Copenhagen, Denmark

Nov 2013	How to lead without being the leader (2 days), www.fyi.dk
Aug & Oct 2010	Project Management courses (2+2 days). Lundbeck courses, www.implementconsultinggroup.com
Dec 2006	Project Management course, DIEU (now Mannaz) (3 days),
Jun 2003	Diploma as Medical Sales Representative, (Module 1: Anatomy/Physiology; module 2: Therapeutic areas; module 3: Medical Legislation; module 4: Pharmacology). THE DANISH ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY (LIF).
Nov 2001	Diploma in GCP monitoring, DANISH ASSOCIATION OF THE PHARMACEUTICAL INDUSTRY (LIF)
Apr 2000	Master of Science in Pharmacy, - master thesis in neurobiology. ROYAL DANISH SCHOOL OF PHARMACY – Copenhagen (NOW THE FACULTY OF PHARMACEUTICAL SCIENCES AT COPENHAGEN UNIVERSITY)
June 1991	Baccalaureate. LEMVIG HIGH SCHOOL – Lemvig

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LANGUAGES

Danish Fluently – written and oral
English Fluently – written and oral
French Fluently – written and oral

Private

3 Children - David 22 years, Sara 19 years and Sofie 15 years

Hobbies: Dancing Salsa/bachata, winter bathing, running, diving, travelling

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