

CURRICULUM VITAE

PERSONAL DATA

Name : Huisman Cecilia .A.M

BIG registration : 19010950030

First name (names) : Cecilia Adriana Maria

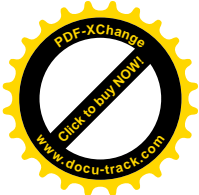
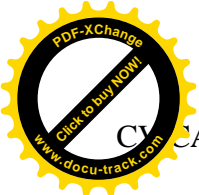
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Nationality : Netherlands

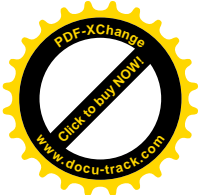
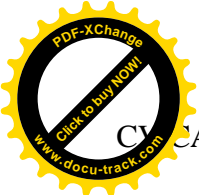
Current function: : ***Director, GCP trainer, CCRC, CRA***
Since 2000
Research professional in clinical research since 1990

Website : www.penthecia.nl



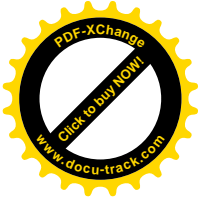
EDUCATION/COURSES

| | |
|-------------------|---|
| 1973 – 1975 | Pre-nursing school, nursing –home; certificate |
| 1975 – 1979 | Nursing-school, University Hospital Rotterdam ‘Dijkzigt’. Certificate, BIG registration nr:19010950030 |
| 1980 - 1984 | Academy of Ballet, teacher in dance; certificate |
| 1987 – 1990 | Academy of Physical therapy, The Haque and Rotterdam; no certificate |
| 1995 | Course “patient information”, Utrecht, certificate |
| 1996 | EORTC course: ‘cancer and clinical trials’, certificate |
| 1997 | ICH-GCP course, Wageningen , certificate |
| 1998 | Management “ middenkader”, University Hospital Rotterdam |
| 1998 | Basic statistics, EORTC Brussels, certificate |
| 1999 - 2000 | Post-graduate program (1,5 year) for Research Nurses Rotterdam, (RN / CCRC) certificate |
| 2002 | Course Project management (4 day’s), Docs Int., certificate |
| 2004 | ZONMW, ‘cursus aanvragen subsidie “ |
| 2007 (november) | medical statistics, Novartis oncology in collaboration with CRA Academy (2 days) |
| 2008 (april-jan.) | coachings skills (10 days), Transfergroep Rotterdam |
| 2008 (February) | Wintercourse paediatric research, EMC Rotterdam |
| 2008 (February) | Interventional studies, EMC Rotterdam |
| 2008 (May) | How to perform an audit |



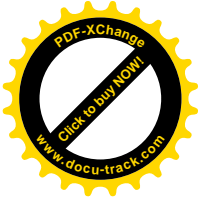
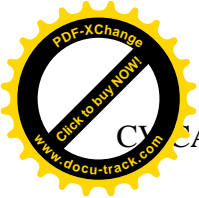
WORKING EXPERIENCE:

| | |
|----------------------|--|
| 1973 -1975 | Nursing home for elderly, Simeon en Anna, nursing care giver |
| 1975 – 1979 | University Hospital Rotterdam, Dijkzigt, different department as a student nurse |
| 1979- 1984 | University Hospital Rotterdam , 'Dijkzigt' Department neurosurgery, registered nurse |
| 1984 – 1990 | Freelance nurse in several hospitals in Rotterdam, Nijmegen |
| 1984 – 1987 | Professional dancer, Dancecompany Djazzex, the Haque |
| 1976 - 1990 | Trainer / teacher in ballet/dance (classical, modern and jazz), amateurs, adults and children |
| 1990 – 1995 | University Hospital Rotterdam, Dijkzigt, Department of Hematology, research nurse and data manager Study management and data management |
| 1995 – 2000 | University Hospital Rotterdam 'Dijkzigt' Department of Hematology, research coordinator Project management, study management and data management |
| 2000- present | Founder of Penthecia company: research management and coaching in clinical trials, director. Activities: <ul style="list-style-type: none">- Education of research nurses, members of IRB, students, investigators- Coaching (research) personnel- Coordinator (multicenter) clinical trials (project- and subject and data management).- Preparation and implementation of clinical trials, sponsor and investigator initiated (phase 1-4)- Study administration; ISF and TMF- Development Patient information sheet and IC form- Development source documents- Monitor clinical investigations, assuring that protocol is followed in line with the applicable regulations and study procedures and data source verification- Feasibility analyses of clinical trials- Estimation of study budget of a clinical project per site / department- Trials supported since 2000: oncology, hematology, neurology, psychiatry, vaccines, urology, diabetics, cardiology, pain management, phase I (volunteers and oncology), nutrition trials. |



EDUCATIONAL AND TEACHING RESPONSIBILITIES/experiences

| | |
|-----------------|--|
| 1998 | lecture ICH-GCP medical students University Erasmus Rotterdam |
| 1998 – present | active member of the Dutch Research Nurse Job Profile working group. |
| 1998 – 2005 | training research nurses at the post-graduate program for research nurse and clinical coordinator (RN/CRC), Rotterdam, coordinator module “study management and skills lab” and supervision trainee |
| 2005 | transformation of the post graduate program for RN / CRC into competence oriented education and practical need, including portfolio, practical assignments and assessments |
| 2005- present | trainer, assessor, supervisor and adviser of education of the post-graduate program for research professionals (RN/CRC) Topics: feasibility analyses, Informed consent procedure and how to write patient information sheets, safety parameters, definitions and how to report, laboratory analyses, recruitment of trial subjects, how to estimate study budget, CRF and source docs. |
| 1999 – present | founder and president of the Dutch Research Nurse Association: Nederlandse Vereniging voor Research Verpleegkundigen (NVRV). |
| 2000- present | coaching research professionals in hospitals and research sites |
| 2001- 2002 | trainer University Roeselare Belgium, Research Coordinators |
| 2001- 2005 | trainer ICH-GCP training Wageningen (Anjo Strik) 5-6 times per year, beginners and advanced research professionals |
| 2005- 2006 | member of the evaluation committee of the program immune- and targeted therapy at the VU, Amsterdam |
| 2005 - present | trainer ICH-GCP training Wageningen (Anjo Strik) advanced research professionals once per year |
| 2006 (December) | “counseling” for research professionals UMC Utrecht, department obstetrics |
| 2007 -present | yearly presentation : ‘patient safety under the new regulations’, lecture at the graduate school of drug exploration Groningen, program: “good research practices” |
| 2007 (July) | trainer ICH – GCP, in company course department of cardiology Vlietland Hospital Vlaardingen |



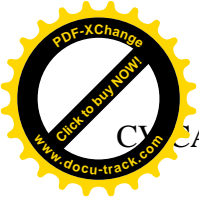
2007 - present

design, construction and performance

yearly an one week coaching and training program for CRC's from Japan. Design, construction and performance of the course

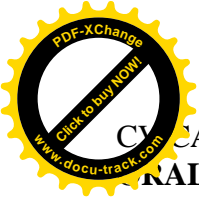
2007-present

several GCP courses and workshops at the investigational in the Netherlands



MEMBERSHIP (medical and research)

- 1996 – present VvOV, Dutch oncology nursing group
From 2007 V&VN oncology
- 1996 – present NWOD, Dutch working group for data manager
From 2007, association of data managers in oncology
- 1996 – present EORTC, Oncology nursing group
- 1997 – 2000 Typhon: Bone marrow registry
- 1998 - present VWIN, Dutch Biotherapy working group
Since 2004 SIG immunotherapy
president since January 2004 of SIG Bio-/ immunotherapy
since 2007: SIG immuno-/targeted therapy
- 1998 – 2000 LOOV, Dutch working party oncology-nurses
- 1999 – present European Bone marrow Transplantation, nurse group
- 1999 – present NVRV, Dutch Research Nurse Association;
Nederlandse Vereniging voor Research Verpleegkundigen en overige
professionals, president since January 1999
- 1999 – present ACRP, Association Clinical Research professionals
Chapter Chair ACRP-NL since 2001
- 2001 – present NvFG: Dutch association for Pharmaceutical Physicians
- 2002 – 2008 Member of the advising committee (oncology) Roche BV
- 2004 – present member of the Federation of biomedical scientific societies (FMWV)
- 2005 – Dec. 2006 member of the Patient Information forums (PIF) working group of the
CCMO
- 2005 – present member of the EFGCP, European Forum GCP
- 2006 - present member of the editorial committee of the St. CKWO, Stichting
Certificering Klinisch Wetenschappelijk Onderzoeker
Since may 2009 board member
- 2006 – present member of the Dutch working party ‘patient Access’
- 2008- present member of the dutch clinical trial foundation, forum education



- 2001 poster: the research nurse job profile, EBMT, ECCO
- 2001 ECCO: oral: Mabthera a practical approach
- 2002 VvOV congres: oral MabCampath: “onderschatting van de lange termijn effecten van MabCampath”
- 2003
 - ECCO, study nurse group EORTC: oral: “How the European Directives effects your work as a CRC”
 - WCN congress oral: “Is quality depended or independent?”
- 2004 VvOV, oral immunotherapy session, the use of EPO
- 2005 VvOV, oral immunotherapy session
- 2006
 - Applied Clinical Trial congress, oral, “*The patient under the new regulations*”
 - debate leader, workshop session immunotherapy of the national congress for oncology nurses meeting.
- 2007
 - Ecco, sept 2007 Barcelona, poster presentation, e.a. “how to reach immuno-/targeted therapy with a SIG
 - Oral, ACRP, 15th June chapter meeting: competence and skills of a research professional (RN/CRC)
 - ACRP, 28th June chapter meeting, workshop advanced GCP
 - Oral, 11th October Hospital Enschede (MST): “clinical research professional, to be or not to be?”
 - oral, Clinical Research Nurses Association and Associate Members, Canterbury “science v Patient Care: Complement or Conflict?” 4th October
 - Oral, 1st of November, Zeist GSK, intensive care research platform: “why become a member of an organization /association?”
 - Berlin, Applied clinical trial congress, workshop 30th October “the challenges at the investigators sites, how to improve”
 - national NVRV / ACRP meeting 15th November, “ethical dilemmas in research’
 - oral: strategy and outcomes of the working group patient information letters, of the CCMO
- 2009 oral, ACRP meeting, CRC versus CRA

Yearly organized ACRP dutch chapter meetings (3/y) and national conferences (1/y), from **2001 – 2009**
 Yearly involved in the national meetings of the NVRV and oncology association (V&VN oncology)