NUSAGE - PAREXEL
Postgraduate Certificate in Clinical Trial Management

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Bettina Merz-Nideroest
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PAREXEL International and the National University of Singapore Academy of GxP Excellence (NUSAGE) have come together to offer a 10-week comprehensive and practice-oriented Postgraduate Certificate Programme in Clinical Trial Management.

Drawing on a decade of experience in Germany, the course is designed and taught by PAREXEL experts at one of the world’s most prestigious universities, and is intended to facilitate entry into one of the most rapidly expanding industries: Clinical Research.
PAREXEL International

- One of top 5 Contract Research Organisations (CRO)
- Established in 1982: over 30 years of experience conducting clinical research for the biopharmaceutical industry
- Incorporated in 1983 by Josef H. von Rickenbach, Chairman and CEO
- Headquarters in Waltham, MA, USA
- More than 14,000 employees: 1,700 in Germany
- Truly global presence: 76 office locations in 45 countries
- Breadth of biopharmaceutical services from Phase I-IV clinical trials
May 2001: PAREXEL-Akademie founded in Berlin, Germany

Over 1700 participants in courses to date:

- 680 Study Nurses
- 549 Investigators
- 443 Postgraduate Students
- 65 Undergraduate Students

plus several hundred professionals from numerous pharmaceutical companies
From local to global

July 2012: renamed Academic Institute, a division of PAREXEL International Learning and Development

Aims:
• to partner with academic institutions worldwide in order to provide top quality, accredited education and training in clinical research

• to provide more efficient entry routes to an international career in clinical research

• to be a leading provider of external training in all aspects of clinical trial management for newcomers to the industry, career changers and clinical research professionals

• to train PAREXEL internal staff and new hires
Portfolio

PAREXEL Academic Institute

- Postgraduate Certificate Programmes
- Training for the Pharma Industry
- ICH-GCP Training for Site Staff
- Japan Oncology Academy
- Bachelor of Science in Clinical Research (BSc)

Programme funded by German Government

Joint programme with NUSAGE, University of Singapore

Joint programme with Salem State University

Planned programme with Kyoto Pharmaceutical University (KPU)

Validated by the University of Wales
Postgraduate Certificate Programmes

Certificate in Clinical Trial Management in EMEA
Delivered at PAREXEL, Berlin, funded by German Employment Agency
3 x year (January, May and September 2013)

Certificate in Clinical Trial Management in APAC
Joint programme with the National University of Singapore, NUSAGE
1 x year: May 2013

Certificate in Clinical Trial Management in North America
Joint programme with Salem State University (SSU)
3 x year (February, June and October 2013)

Certificate in Clinical Trial Management in APAC Region (Japan)
Joint programme with Kyoto Pharmaceutical University (KPU)
3 x year: Aug 2013 (pilot)
COURSE OVERVIEW
### Course Structure

<table>
<thead>
<tr>
<th>Qualification</th>
<th>Postgraduate Certificate in Clinical Trial Management</th>
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<tbody>
<tr>
<td><strong>Course structure</strong></td>
<td>4 modules taught sequentially</td>
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<tr>
<td><strong>Delivery</strong></td>
<td>One week full-time face-to-face training (30 hours)</td>
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<td></td>
<td>One week self-directed learning (30 hours)</td>
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<tr>
<td><strong>Academic value</strong></td>
<td>4 x 4 Modular Credits (MC) = 16 MC (24 ECTS)</td>
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<tr>
<td><strong>Course length</strong></td>
<td>10 weeks: 8 teaching weeks</td>
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<tr>
<td></td>
<td>1 revision week</td>
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<tr>
<td></td>
<td>1 examination week</td>
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<tr>
<td><strong>Assessment</strong></td>
<td>A 2-hour written examination for each module.</td>
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<tr>
<td><strong>Faculty</strong></td>
<td>Lecturers from PAREXEL Academic Institute and NUS</td>
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<tr>
<td><strong>Venue</strong></td>
<td>Department of Pharmacy, Faculty of Science</td>
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<td>National University of Singapore</td>
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Selection Procedure

**Prerequisites**

Bachelor degree in Medicine, Pharmacy, Life Sciences or related major.

IELTS 7.0 or TOEFL equivalent for applicants who attained their degrees (part or entire programme) outside of UK, USA, Canada, Australia or New Zealand, and/or discretionary admission through interview and a pre-admission assessment. (Language requirement waived for those who have completed their studies in English)

Valid driving licence to facilitate future employment

**Application procedure**

Online application form to NUSAGE

**Selection procedure**

Assessment Centre comprising:

- Interview
- Aptitude test
<table>
<thead>
<tr>
<th>Week</th>
<th>Dates</th>
<th>Topic</th>
<th>Hours Type</th>
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<tbody>
<tr>
<td>Week 1</td>
<td>13 - 17 May 2013</td>
<td>Drug Development Process</td>
<td>30 hrs contact</td>
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<tr>
<td>Week 2</td>
<td>20 – 24 May 2013</td>
<td>30 hrs directed learning</td>
<td></td>
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<tr>
<td>Week 3</td>
<td>27 – 31 May 2013</td>
<td>Regulatory Affairs</td>
<td>30 hrs contact</td>
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<tr>
<td>Week 4</td>
<td>03 – 07 June 2013</td>
<td>30 hrs directed learning</td>
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<tr>
<td>Week 5</td>
<td>10 – 14 June 2013</td>
<td>Conducting Clinical Research</td>
<td>30 hrs contact</td>
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<tr>
<td>Week 6</td>
<td>17 – 21 June 2013</td>
<td>16 hrs directed learning</td>
<td></td>
</tr>
<tr>
<td>Week 7</td>
<td>24 - 28 June 2013</td>
<td>Client Relationship Management</td>
<td>30 hrs contact</td>
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<tr>
<td>Week 8</td>
<td>01 – 05 July 2013</td>
<td>30 hrs directed learning</td>
<td></td>
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<tr>
<td>Week 9</td>
<td>08 – 12 July 2013</td>
<td>Revision / Consultation</td>
<td></td>
</tr>
<tr>
<td>Week 10</td>
<td>15 – 18 July 2013</td>
<td><strong>1 x 2-hour examination per module</strong></td>
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THE DRUG DEVELOPMENT PROCESS

Matthias Grossmann, MD, PhD
Clinical Pharmacologist
Pathophysiologist
Vice President and Principal Consultant
Lecturer, PAREXEL Academic Institute
History of Drug Development

Before 1800
  • use herbal remedies
After 1850
  • isolate the active principle
  • understand symptoms of a disease
After 1920
  • recognize the cause of a disease (insulin, penicillin)
  • discover putative target
After 1970
  • understand immunology and genetics
  • produce human-specific compounds/biologicals
After 2000
  • an era of individualized medicines?
The Drug Development Process
Drug Development: Success Rate

- Only 1 out of 50 drug candidates reaches clinical testing
- Only 1 out of 5 of these drug candidates reaches the market
- Clinical development is twice as expensive as candidate selection
Learning Too Little Too Late

KNOWLEDGE vs. TIME / MONEY

Preclinical Phase I-IIa Phase IIb Phase III Phase IV

Desired Current Market Withdrawal!
Learning Too Little Too Late

- Preclinical
- Phase I-IIa
- Phase IIb
- Phase III
- Phase IV

KNOWLEDGE vs. TIME / MONEY

Desired vs. Current
Orloff and Stanski 2009

**Target**
- Target discovery and validation

**PoC**
- PoC clinical trials

**Approval**
- Clinical development

**Exploratory phase**
- Apply biomarkers, modelling and simulation, and advanced statistical methodology
- Demonstrate PoC and establish dose selection

**Confirmatory phase**
- Apply innovative tools and clinical trial designs such as adaptive or seamless studies
- Identify target patient population, confirm optimal dose and dosing regimen and establish the benefit/risk ratio
Drug Development

- is expensive
- time consuming
- often fails
- time is limited due to patent expiry

→ good planning is of paramount importance

Good planning needs good understanding...
Module Two

REGULATORY AFFAIRS

Bettina Merz-Nideroest, MPharm
Pharmacist
ICH-GCP Expert & Senior Trainer
Lecturer, PAREXEL Academic Institute

Edmund C W Leong, PhD
Senior Director, Global Research Operations
Clinical Operations Leaders & Study Start-Up Asia Pacific
Lecturer, PAREXEL Academic Institute
An Early Clinical Trial

Dr. James Lind and Scurvy
Royal Navy Surgeon aboard HMS Salisbury
Scurvy: disease caused by deficiency of Vitamin C

20th May 1747
12 scorbutic sailors divided into six pairs

1) a quart of cider daily
2) 3 x 25 drops of elixir of vitriol (sulfuric acid)
3) two spoonful of vinegar three times a day
4) half a pint of sea-water
5) two oranges and one lemon
6) a spicy paste (garlic) plus barley water

→ Group 5 experienced a remarkable recovery
Conduct of Clinical Trials

• Would it still be possible nowadays to conduct the study as Dr. Lind did in 1747?

• What are the **requirements** for starting and conducting a Clinical Trial?

• What **guidelines** and **laws** must be followed?

• Who are the **key players** in clinical research?

• What are their **roles** and **responsibilities**?

• What **documents** are essential?

→ Regulatory Affairs Module!
CONDUCTING CLINICAL RESEARCH

Claudia Richter
MSc in Medical / Nursing Education
Senior Clinical Research Associate
Senior Lecturer and Course Leader,
PAREXEL Academic Institute
Process of a Clinical Trial

The Clinical Trial Activities

- Protocol Approval
- Investigator Selection
- IRB/IEC Approval Process
- Investigator Training and Patient Selection
- Clinical Trial Report and Marketing Authorization
- Statistical Analysis
- Data Collection and Review
What Happens on Site?

This module addresses the following questions:

• How are patient safety and data integrity assured in Clinical Trials?

• What does a Clinical Research Associate (CRA) have to do and why?

• Why is it so interesting to work with site staff in Clinical Trials?

• What are the challenges for a CRA in Clinical Trials?
CRA - Responsibilities and Interactions

- Investigators and site staff
- Client (Sponsor)
- Vendors
- Other functional groups
CLIENT RELATIONSHIP MANAGEMENT

Sabine Brunschoen-Harti, PhD
Scientist
Director Operations Process, Quality & Training
Lecturer, PAREXEL Academic Institute
Client Relationship Management

This module deals with the following topics:

- Managing studies with special requirements
- The importance of good communication
- Good document practice requirements
- Preparing for audits and inspections
- Detecting and managing non-compliance and fraud
The Importance of Good Communication

During study visits
• Addressing quality issues
• Clarifying issues

Good Documentation Practice Requirements
• Data, documents, signatures

Advanced Monitoring Visit Report Writing
• Addressing the requirements of ICH/GCP
• Meeting client expectations
• Meeting regulatory requirements
Quality Control

Identifying, managing and dealing with:
- poor performance
- non-compliance
- fraud

Audits and Inspections:
- Preparation with site
- Communication with investigators
- Communication with inspectors
- Do’s and Don’ts...
- Common Findings
ASSESSMENT
Assessment and Marking

**Assessment**
The course is assessed via 4 x 2-hour written examinations at the end of the course (1 per module) during exam week.
The exams are a mixture of multiple choice, short answer and case study questions.

**Marking**
The Postgraduate Certificate is marked according to the UK marking system:

- 70% and over: Distinction
- 60% - 69%: Merit
- 40% - 59%: Pass
CAREER OPPORTUNITIES
Proven Success

Over 450 graduates have completed our postgraduate courses in Germany

• 92% found jobs on completion of the course
• 50% received job offers before the end of the course

Past PAREXEL-NUSAGE course graduates have gone on to work in Singapore, Australia and Taiwan as:

• Clinical Monitors
• Clinical Trial Specialist in Study Start-Up
• Project Assistants to Clinical Operations Leaders
Possible Careers in Clinical Research

Clinical Research Associate, Clinical Monitor, Clinical Monitoring Associate, Clinical Trial Monitor, Clinical Research Specialist, Clinical Research Assistant, Field Based Monitor, Medical Writer, Drug Supply Manager, Clinical Site Manager, Clinical Trial Assistant, Study Coordinator, Clinical Research Coordinator Clinical Study Manager, Clinical Manager, Clinical Research Manager, Director Clinical Research Management, Clinical Project Scientist, Project Management Assistant, Clinical Project Manager, Medical Field Manager, Clinical Trial Manager, Clinical Scientist, Drug Safety Manager, Data Entry Assistant, Clinical Writer, Manager Drug Regulatory Affairs, Regulatory Specialist, Head of Drug Safety, Regulatory Affairs Manager, Manager Drug Safety, Data Manager, Database Manager, Clinical Data Manager, Clinical Programmer, Clinical Data Associate, Database Administrator, Senior Clinical Data Coordinator, Line Manager, Medical Service Liaison Manager, Field Application Specialist Molecular, Clinical Trial Specialist
Employment Opportunities

Should employment opportunities at PAREXEL arise during the course, students will be encouraged to apply for them and will be given priority over external candidates.

Upon completion of course, the best students will be interviewed for first priority consideration for suitable vacancies in the APAC region.
FREQUENTLY ASKED QUESTIONS
How will this course benefit me?

How can taking this course help me with a future career in clinical research?

The extensive use of role plays and true-to-life case studies gives you insight into the workings of the clinical research industry.

This gives NUSAGE-PAREXEL graduates a huge advantage over candidates with no relevant knowledge or qualifications.

You will be interviewed for any appropriate and available openings at PAREXEL. However, there can be no guarantee of either a job or of a paid work placement on completion of the course.
Is the course suitable for fresh graduates?

I am a fresh graduate. Can I apply for this course?

Yes, this course will be very beneficial to fresh graduates with relevant degrees seeking a fulfilling career in Clinical Research.

Career changers are also welcome.
Can I study part-time?

I am currently employed but would like to take this course. Can the course be offered as a part-time via distant learning instead of full-time?

Unfortunately, no.

Clinical research is a service industry and the importance of interpersonal skills cannot be underestimated. Our experience has shown that such skills are best taught and developed live and face-to-face.

The very hands-on style of teaching is one of our unique selling points that distinguishes us from other training providers.
Can I return to my normal job during the Directed Learning weeks?

During the Directed Learning weeks students are given written assignments to complete. Many of these done in student groups, so physical attendance is necessary.
Questions?