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GERMAN CANCER RESEARCH CENTER
IN THE HELMHOLTZ ASSOCIATION

50 Years – Research for A Life Without Cancer

Career Day
CLINICAL RESEARCH

Friday, September 23rd 2016, 8:45-17:30

DKFZ, Communication Center

Session 1: FROM TRANSLATIONAL RESEARCH TO CLINICAL RESEARCH
DKTK + NCT

Session 2: PHARMA PERSPECTIVE - CRAs & CLINICAL MANAGERS
Quintiles + Roche + CureVac AG + Fresenius KABI

Session 3: DRUG SAFETY & MEDICAL AFFAIRS
Boehringer + KKS + Leo Pharma + AstraZeneca + MediTech Media

Round table and open discussions
Visit our website and DKFZ Connect for more details!

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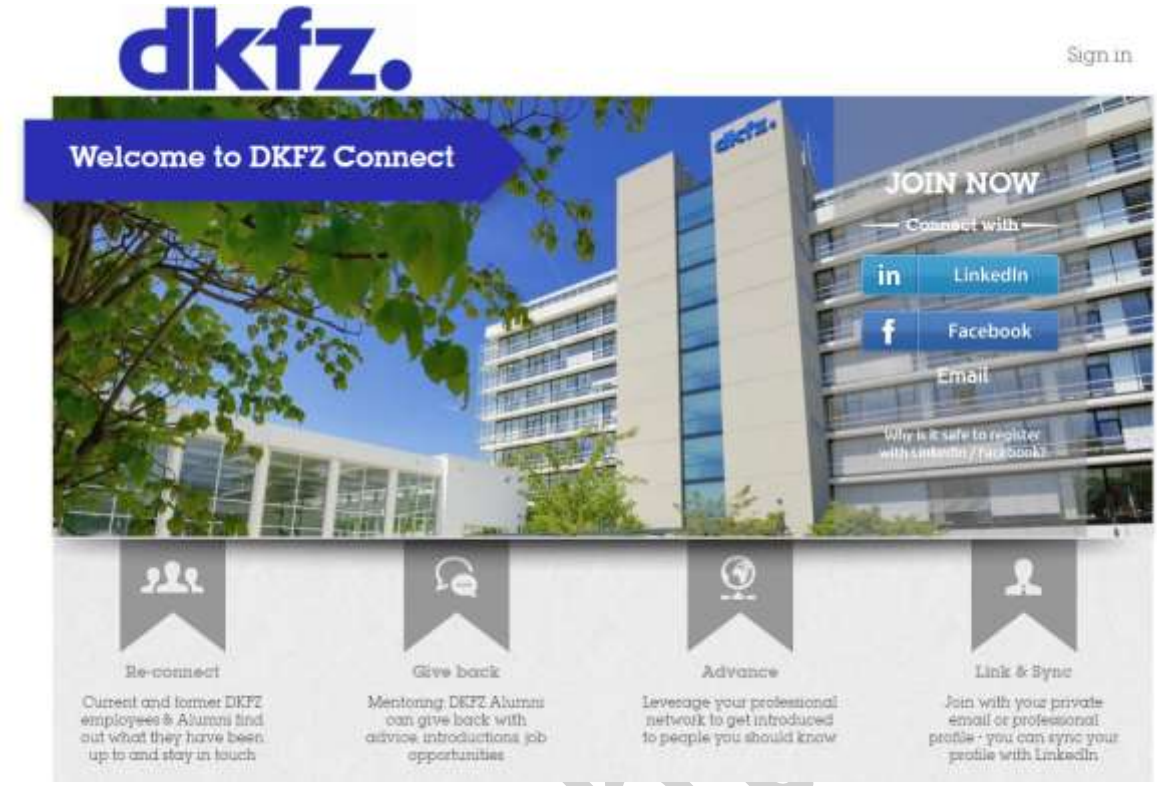
the RNA people®

Welcome Speakers, Participants & Followers on [DKFZ-Connect]!



To follow the Career Day Online, post on

www.dkfz-connect.de and twitter with

#clinrescareerday

A selection of tweets will be published as a summary of the event!

Welcome Address

Dear Attendees,

It is an absolute pleasure for me to welcome you today to our Career Day 'Clinical Research'.

When we first started putting together the program, we looked through DKFZ Alumni for people working (or who have worked) in the field of clinical research. We were surprised by the huge numbers of Alumni, the vast variety of jobs related to clinical research and the great willingness of many Alumni to share their knowledge and experience, enabling such a Career Day as today. **Hence, first and foremost, I would like to very much thank all our speakers for their enthusiasm and time.**

My colleagues did a very good job in selecting and inviting fantastic speakers with very fascinating jobs ranging from: early translational research and its transition to clinical trials, the execution and monitoring of clinical trials, regulation, and the maintenance of drug safety. Not only will we get the chance to listen to their talks today and learn about their career paths, but also get the chance to ask questions. I would like to encourage you to seize this opportunity and make use of the round table discussions, open discussion rounds, coffee breaks and the reception in the evening to do so (program on page 4 or back of this booklet).

At this point, I would like to thank my eleven co-organizers (picture below): it was an absolute pleasure to organize this day together with you. Moreover, on behalf of the whole organizing team, I would like to thank the Career Service and the Career Day Steering Committee for providing this opportunity and encouragement to develop and explore our own capabilities in this "hands-on Project Management" advanced training (more info on pages 43/44).

Finally, we would like to express our gratitude towards the DKFZ Management Board, without whom this Career Day would not have been possible. Thanks also to the many other DKFZ staff that helped and supported us during the organization process. I would like to refer to page 45 for a complete list of all our generous helpers, which definitely would go beyond the scope of this one page welcome address. Thank you all!

Lisa Schardt
Coordinator of the Career Day 'Clinical Research'

Organizing Team of the Career Day 'Clinical Research'

Table of Contents

YOUR FEEDBACK is important for us!

Please answer a few questions at:

www.surveymonkey.de/r/MXXX5FZ

Program

08:00 **On-site Registration**

09:00 **Session I: "From Translational Research to Clinical Research"**

Prof. Klaus Kopka (DKTK) & Prof. Frederik Giesel (DKTK)

Dr. Claudia Trierweiler (NCT, Project Manager)

10:00 **Coffee Break**

10:30 **Session II: "Pharma Perspective – CRAs & Clinical Managers"**

Dr. Antonino Natoli (Quintiles, Senior CRA, Frankfurt)

Dr. Alberto Calabrò (Roche, Global Compassionate Use Coordinator, Basel)

Agata Bloswick (Quintiles, Clinical Program Director, Krakow)

Dr. Sven Grösgen (Roche, Clinical Operations Study Manager, Mannheim)

11.30 **Lunch Break**

12:50 **Session II (continued)**

Dr. Sabine Brutlach (CureVac AG, Clinical Project Manager, Tübingen)

Dr. Carolin Blume (Fresenius KABI, Clinical Project Manager, Bad Homburg)

13:20 **Panel Discussion with Speakers**

14:00 **Round Table Discussions with Speakers (Coffee Break)**

14:30 **Open Discussions / Networking**

14:50 **Session III: "Drug Safety & Medical Affairs"**

Dr. Melanie Ruppel (Boehringer Ingelheim, Head of Global Submission Services, Ingelheim)

Dr. Jacek Hajda (KKS, Head of Pharmacovigilance and Scientific Project Manager, Heidelberg)

Dr. Nathalie Fiegler (Leo Pharma, Medical Information Manager, Frankfurt Area)

Dr. Sebastian Pieperhoff (AstraZeneca, Medical Science Liaison Manager, Mainz)

Dr. Olga Ucar (MediTech Media, Medical Writer, Manchester)

16:00 **Round Table Discussions with Speakers (Coffee Break)**

16:50 **Closing Remarks - Announcements**

17:00 **Reception: Open Discussions / Networking**

Clinical Trials – An Overview

Clinical trials are research studies of human subjects that are designed **to investigate the safety**, **efficacy** and **effectiveness of novel therapeutics**, such as cancer drugs. First, pre-clinical studies including extensive *in vitro* (*e.g.* cell culture) and *in vivo* (animal) experiments are necessary to obtain pre-clinical data. Once promising pre-clinical data are available, a clinical trial can be designed. Most drugs have to be tested in healthy volunteers first, but cancer drugs are often directly tested in cancer patients because of ethical considerations not to expose healthy people to the cytotoxic side effects of many cancer drugs.

There are three main phases in clinical trials (phase I to III), which differ in the purpose as well as in the amount of patients enrolled. However, some trials have an earlier stage called phase 0, and there are some phase IV trials done after the drug has been licensed.

Phase 0: First study in a small number of patients to find out if a drug (given in a very small dose) behaves in the way researchers expect it from their laboratory studies.

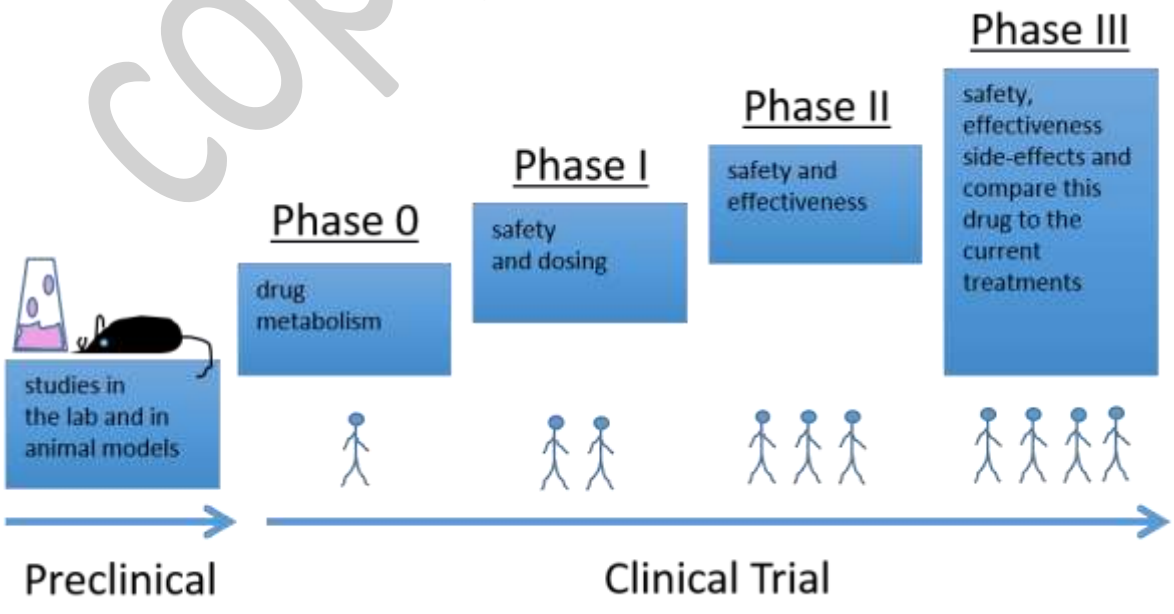
Phase I: Testing in only a small group of people (tens) for: 1) Human safety (how much of the drug is safe to give, 2) Side effects, 3) Effect on the disease

Phase II: Testing for efficacy and further safety evaluation, larger group of people (up to 100)

Phase III: Testing for efficacy by comparing the intervention to other standard therapies and monitoring of adverse events, larger group of people (from several hundred to several thousand)

Phase IV: After the drug or treatment has been marketed, in order to gather information on the drug´s effect in various populations and any side effects associated with long-term use.

Enrollment of volunteers and patients for clinical trials has to follow the Declaration of Helsinki, a set of ethical principles for Medical Research, involving human subjects. Each patient has the right to withdraw from a clinical trial at any time. To ensure patients´ integrity, names of patients in the clinical trial are pseudonymized (patient´s name can be recovered from authorized persons only) or anonymized (patient´s name cannot be recovered at all).



Clinical Trials – An Overview

To generate most valuable clinical data, clinical trials should be **prospective, controlled, randomized and double blinded**. Prospective describes the fact that the data is generated throughout the clinical trial. A controlled clinical trial has at least two groups – a treatment group and a placebo control group – and is randomized if patients are randomly assigned to these groups. The patient doesn't know to which group he/she has been assigned (single blinded or double blinded if the medical doctors do not know this either).

Clinical trials can be categorized into two groups: **clinical trials testing pharmaceuticals (AMG-study)** following the German law on pharmaceuticals (*Arzneimittelgesetz*) or **clinical trials testing medicinal products (MPG-study)** according to the German law on medical products (*Medizinproduktegesetz*). Clinical trials can either be of **commercial or non-commercial** character. Often pharma companies conduct clinical trials with the intention to have their novel drug approved for open use. Once the pharma company supplies the drug and finances to conduct the clinical trial, this is named a commercial clinical trial. So called Investigator Initiated Trials (IITs) are not financed by pharmaceutical companies, however the drug might still be supplied by a pharma company to be used in the IIT.

In Germany, **submission of clinical trials** follows defined rules. Regarding clinical trials that test pharmaceuticals, the study protocol has to be submitted at the Competent Authority ("*Bundesoberbehörde*") and the local ethics commission. The responsible "*Bundesoberbehörde*" is selected accordingly to the pharmaceuticals used in the clinical trial. Hereby, clinical trials including allergens, vaccines and biotech products have to be approved by the Paul Ehrlich Institute (PEI). All others are sent for approval to the BfArM (*Bundesinstitut für Arzneimittel und Medizinprodukte*). An approved clinical trial has to be announced to the "*Landesbehörde*". For the city of Heidelberg this is the "*Regierungspräsidium Karlsruhe*".

The clinical trial study protocol is a document that describes how a clinical trial will be conducted (e.g. the objective(s), design, methodology, statistical considerations and organization). It ensures the safety of the trial subjects and integrity of the collected data. The study protocol also names the **sponsor** who can be an individual, an institution, a company or an organization, who is responsible for inducement, organization and funding of the clinical trial. To collect the study specific data, which have been defined in the study protocol, a **case report form (CRF)** is used. The case report form is designed to collect the patient data in the clinical trial. It represents a significant part of the clinical trial and can affect the success of a study.

Each **clinical trial** has to define **endpoints.** In the oncology field these endpoints include OS: Overall Survival, PBS: Progression Free Survival; EFS: Event free survival; CR: Complete Response; PR: Partial Response. Analysis of these endpoints will finally allow assessing the therapeutic efficacy of novel pharmaceuticals compared to the so far standard of care.

Accompanying the clinical trial can be a **translational research** part, which tries to elucidate the molecular treatment-induced effect of the tested pharmaceutical. This research analysis can be useful to detect molecular biomarkers (such as expression of a certain molecule/pathway, frequency of certain cell populations or gene marker), which are of prognostic value regarding the administration of the novel pharmaceutical.

This summary was written by the Career Day Organizing Team without claim to completeness.

Sources: www.bfarm.de ; www.pei.de; www.medizinische-fakultaet-hd.uni-heidelberg.de/

PROF. KLAUS KOPKA

LinkedIn ✓ ResearchGate ✓

Professor; Head Division of Radiopharmaceutical Chemistry

at DKFZ, Research Program Imaging and Radiooncology

SESSION 1: FROM TRANSLATIONAL RESEARCH TO CLINICAL RESEARCH

WORK EXPERIENCE

Head Division of Radiopharmaceutical Chemistry at DKFZ (since 04/2013)

Head Working Group Radiochemistry/Radiopharmacy at the University Hospital Münster, Dept. of Nuclear Medicine (07/1997 - 03/2013)

EDUCATION

PhD/MD obtained: October 1996

Diploma in Chemistry at University of Münster

TELL ME MORE...

What is the function and responsibility of your current role?

Head Division of Radiopharmaceutical Chemistry

“From Translational Research to Clinical Research”

PROF. FREDERIK GIESEL

LinkedIn ✓ ResearchGate ✓

Professor; Vice Chair of Nuclear Medicine, Department of Nuclear Medicine

at University Hospital Heidelberg

SESSION 1: FROM TRANSLATIONAL RESEARCH TO CLINICAL RESEARCH

WORK EXPERIENCE

Vice Chair of Nuclear Medicine at the University Hospital Heidelberg (since 01/2014)

Senior Resident Nuclear Medicine at the University Hospital Heidelberg (10/2008 – 12/2013)

DKFZ since 2004

National Institute of Health (NIH) 2001

EDUCATION

MD in Radiology and Nuclear Medicine (Board certified) at University Hospital Heidelberg

PhD/MD obtained: April 2004

TELL ME MORE...

What is the function and responsibility of your current role?

Vice Chair of Nuclear Medicine

- Introducing new molecular tracers into the clinic
- Supervise Residence Doctors in the clinical training
- Establish SOPs (Standard Operating Procedures) in the clinical procedures

DR. CLAUDIA TRIERWEILER

Project Manager for Clinical Trials

at NCT Clinical Trial Center

SESSION 1: FROM TRANSLATIONAL RESEARCH TO CLINICAL RESEARCH

WORK EXPERIENCE

Project Management in Clinical Trials at the NCT Clinical Trial Center (since 2012)

EDUCATION

Scientific Background: Molecular Biology, Hepatocellular Carcinoma

PhD in Molecular Biology at University Hospital Freiburg (2012)

Diploma in Biology (Genetics and Pharmacology/Toxicology) at University Göttingen

TELL ME MORE...

What is the function and responsibility of your current role?

The job profile of a Project Manager for clinical trials at a public institution like the NCT comprises several tasks: Ethical-legal counseling, feasibility and risk analysis, project scheduling, budget planning, contract design and negotiations, preparation of trial documents, regulatory affairs like applications at authorities and ethics committees as well as reporting, definition of supply chains, trial start-up, coordination and financial controlling etc. The Project Manager is the key player for all tasks and people concerned with the trial, with the main function of coordinating all processes. That makes the business multidisciplinary, diversified, and communicative.

What do you enjoy most about the job?

Mostly that every project is special and provides different challenges for which you have to find individual solutions.

“From Translational Research to Clinical Research”

What are the challenges you face in your job?

Unrealistic timelines, managing multiple projects while depending on others to finish their tasks; conflict management between different parties (e.g. PI, monitor, sponsor, regulatory authorities…).

Are there any specific skillsets or qualifications required for this position?

Good soft skills are mandatory, as well as being a team player. Previous experience with handling regulatory affairs with regard to AMG, MPG, GCP-V etc. is also helpful.

Could you recommend any courses, trainings or certificates?

GCP – Prüferkurs

Your number one tip or quote?

Try to get first- hand experience in the field (e.g. internship), because you might decide that the daily work of a Project Manager is completely different from the work of a scientist.

DR. ANTONINO NATOLI

LinkedIn ✓ Xing ✓

Senior Clinical Research Associate (CRA)

at Quintiles

SESSION 2: PHARMA PERSPECTIVE – CRAs & CLINICAL MANAGERS

WORK EXPERIENCE

CRA (Senior CRA since April 2016) at Quintiles (01/2013 – present)

Intern at Pierrel Research (09/2012 – 11/2012)

Qualification Course in Clinical Monitoring, Mibeg-Institute Medizin (06/2012 – 08/2012), Cologne

Postdoc at DKFZ (01/2010 – 02/2012)

EDUCATION

PhD in Biomaterials & Proteomics at University Medicine of the Johannes Gutenberg-University Mainz (2009)

Master in Pharmaceutical Sciences at Università degli Studi di Palermo

TELL ME MORE...

What is the function and responsibility of your current role?

Ensure that a clinical study is conducted in accordance with the protocol and applicable regulatory requirements.

What do you enjoy most about the job?

Teamwork and relationship with colleagues and investigators

What are the challenges you face in your job?

Meet deadlines and work under pressure

“Pharma Perspective – CRAs & Clinical Managers”

What do you think are the general and your personal prospects in this field?

CRA experience prepare to a broad range of roles in the clinical/pharmaceutical field (management, quality control, regulatory…).

Are there any specific skillsets or qualifications required for this position?

Previous experience or a qualification course in clinical monitoring is beneficial but not always required.

What do you think was the crucial factor for you to get your current job?

Personal skills and flexibility

Could you recommend any courses, trainings or certificates?

Clinical Monitoring course at Mibeg in Cologne

Your number one tip or quote?

Always look for the bright side of your frequent travelling

ADDITIONAL INFO

Profile on dkfz-connect.de

Job offers: www.quintiles.com/careers

DR. ALBERTO CALABRÒ

LinkedIn ✓ Xing ✓

Global Compassionate Use Coordinator (CUC)

at Roche / Pharma

SESSION 2: PHARMA PERSPECTIVE – CRAs & CLINICAL MANAGERS

WORK EXPERIENCE

Global Compassionate Use Coordinator at Roche (1 year)

Senior CRA at PPD (6,5 years)

EDUCATION

PhD in Tumor Biology at Ruprecht-Karls-Universität Heidelberg / DKFZ / EMBL (2008)

Master in Biotechnology at University of Bologna

TELL ME MORE...

What is the function and responsibility of your current role?

Coordinate with the different stakeholders the set-up, maintenance phase and closure of compassionate use programs.

What do you enjoy most about the job?

Knowing that my work has an immediate impact the life of patients all around the world. The diversity of the departments in which I am in contacts.

What are the challenges you face in your job?

The biggest challenge is to cope with reactive nature of the programs. Medication will have to reach the patients, independently of his/her geographical location, in no time and without pre-alert (obviously being compliant with all applicable regulation!!!).

What do you think are the general and your personal prospects in this field?

The natural development from this position would be either to move to a “group manager position” or to start as a “drug supply leader”. Due to the variety of stakeholders with whom

a CUC is in contact, it is possible to move into Regulatory, Safety, Medical writing or Scientific lead positions.

Are there any specific skillsets or qualifications required for this position?

- General understanding of the drug mechanism of action and associated patient profile that might potentially benefit from a treatment is a requisite.
- Attention to detail and quick goal oriented thinking is a must in this environment.
- Previous exposure to clinical research environment is advantageous: it guarantee background knowledge of the GxP and drug development process.
- Previous global exposure is surely a plus since it provides an idea of the huge diversity of local requirements.

A general understanding of IT systems (CTMS, Oracle based databases, Office, long term storage file location, etc.) used in clin ops environments is an additional asset.

What do you think was the crucial factor for you to get your current job?

My commitment to the patients, luck, having being exposed to compassionate use program in my previous position and a mixture of the requisite listed above.

Could you recommend any courses, trainings or certificates?

Trainings are a good source of theoretical background, but nothing is like firsthand experience. If nothing else comes along, try to get (even unpaid) a place as data entry in any clinical study currently running in the Heidelberger clinics (there are plenty of them). This will show your commitment and offer you a topic of conversation in a possible face to face interview.

Your number one tip or quote?

Is not only about your qualifications. Technical skills can be learned. It's more about the person you are, your motivation, your passions. Of course your skills must have to fit the company immediate need, but a company will invest in you! Considering the highly dynamic working environment in which we are living, what counts it's you!

ADDITIONAL INFO

Profile on dkfz-connect.de Willing to help

AGATA BLOSWICK

LinkedIn ✓ Facebook ✓

Associate Director Clinical Project Management

at Quintiles

SESSION 2: PHARMA PERSPECTIVE – CRAs & CLINICAL MANAGERS

WORK EXPERIENCE

Global Clinical Project Manager at Quintiles (07/2012 – 06/2015)

Clinical Operations Lead at Pfizer (06/2011 – 06/2012)

Senior Clinical Research Associate, Worldwide Clinical Trials, Inc.(12/ 2010 – 05/2011)

Clinical Project Manager (12/2008 – 11/2010) & **Clinical Research Associate** (11/2006 – 11/2008) at monipol sp. z o.o. Contract Research & Medical Consultants

Intern at DKFZ (07/2004 – 08/2004)

EDUCATION

PhD in Pharmacy: Informed consent design for clinical trials (in progress, expected in 2018) at Jagiellonian University

MSc in Chemistry at Akademia Ekonomiczna w Krakowie; Graduation thesis on Project Management in Clinical Trials

TELL ME MORE...

What is the function and responsibility of your current role?

As Associate Director Clinical Project Management, I oversee execution of six clinical trials in autoimmune diseases. It includes managing the timelines, scope and budget, but also making sure we pick the right countries, resolve any unexpected issues and assure timely project execution.

What do you enjoy most about the job?

Enjoy most enjoy figuring out the patient recruitment strategy. To pick the right countries we need to take into consideration the health policies and standards in the country, availability of drugs on the market, access of patients to the doctors, as well as cultural and political aspects. Once we know we have the right country mix, I enjoy the thrill of meeting the

enrolment goals, working closely with the doctors to find the right patients, and have the whole project team go beyond the expectations and finish enrolment ahead of time.

What are the challenges you face in your job?

Each time a new project starts, as a leader, I need to make sure that we become a team, who will be happy to work together, rely on each other, and deliver on time, even if it means sometimes working harder or overtime. This usually takes a few months, and then it is like a click - all pieces are in place.

What do you think are the general and your personal prospects in this field?

The typical path is Assistant → CRA → Clinical Leader/Lead CRA → Project Manager, or one including Regulatory Submission Specialist in between. There are a lot of opportunities for experienced CRAs, both on-site and home-based.

Are there any specific skillsets or qualifications required for this position?

Definitely soft skills: Management skills, time management, setting goals, clear communication, teaching, mentoring – we learn this at each job, and it helped that I am aware of what I learned in a lab. Other skills: knowledge of languages, cultural awareness, knowledge of geographical/political basics. Understanding the science behind the mechanism of action of a drug, or a disease is important, not very critical at my level but more so on a CRA level, as they typically work very close with the medical doctors. In smaller companies Project/Study managers may be responsible for writing the protocols.

What do you think was the crucial factor for you to get your current job?

At a job interview for my first CRA job, it helped that my boss knew the DKFZ. After being a CRA for 2 months, I knew I wanted to develop to be a Project Manager – it took 18 months of continuous curiosity, learning, attending classes, reading, and preparing. I also spent a month at the University of Yale attending a Summer Internship in Bioethics. I will now take a PM certification.

Could you recommend any courses, trainings or certificates?

Quintiles offers Graduate Trainee Program that prepares future CRAs to start working, where the main pre-requisite is basic scientific degree and knowledge of GCP is required. You can also learn project management (certified by IPMA institute) or take an MBA degree as well, but it is not mandatory at an entry level.

Your number one tip or quote?

I couldn't stand the idea of waiting for decades for a breakthrough discovery in the lab, but working in clinical trials gives me a quicker reward – the patients have to be recruited within a few months and after just few years, I can see "my drug" available for the patients on the market. It's more fast-paced, but it means… it's fast-paced!

ADDITIONAL INFO

Profile on dkfz-connect.de Willing to help

Job offers: www.quintiles.com/careers/graduate-to-quintiles

DR. SVEN GRÖSGEN

LinkedIn ✓

Study Manager Clinical Operations, Global Medical and Scientific Affairs CPS

at Roche Diagnostics GmbH

SESSION 2: PHARMA PERSPECTIVE – CRAs & CLINICAL MANAGERS

WORK EXPERIENCE

Study Manager Clinical Operations, Global Medical and Scientific Affairs CPS at Roche Diagnostics GmbH since August 2014 (2 years)

EDUCATION

PhD in Neuroscience at Universität des Saarlandes (2014)

Diploma in Biology at Technische Universität Darmstadt

TELL ME MORE...

What is the function and responsibility of your current role?

I´m responsible for the development and planning of studies conducted within Clinical Operations, Global Medical and Scientific Affairs CPS. This includes the responsibility to oversee all study related activities and lead the respective study team during planning, execution and analysis of a study.

What do you enjoy most about the job?

Handling complex tasks and interacting with interesting people from various functions in a global environment (e.g. R&D, marketing, project management, regulatory affairs…).

What are the challenges you face in your job?

Handling the regional distances and interfacing with people having different backgrounds.

What do you think are the general and your personal prospects in this field?

My work gives me a lot of insights in different areas and Roche supports the employees in their personal development by offering various trainings and manifold career options.

“Pharma Perspective – CRAs & Clinical Managers”

Are there any specific skillsets or qualifications required for this position?

In general, a scientific background is needed, whereas you also should be interested in various scientific topics, project management and being willing to work in a global environment.

What do you think was the crucial factor for you to get your current job?

Interest in science in general, ability to envision and acknowledge different mindsets and perspectives.

Could you recommend any courses, trainings or certificates?

Acquiring on-the-job experience within and beside sciences in various projects and functions wherever possible.

Your number one tip or quote?

Keep yourself open-minded and be keen in understanding perspectives of other people and/or other functions.

ADDITIONAL INFO

Job offers: www.roche.com/de/careers

DR. SABINE BRUTLACH

Xing ✓

Clinical Project Manager

at CureVac AG, Pharma-Biotechnology

SESSION 2: PHARMA PERSPECTIVE – CRAs & CLINICAL MANAGERS

WORK EXPERIENCE

Clinical Trial Manager at Immatics Biotechnology GmbH (1 year 11 months)

Clinical Research Associate at Scope International AG (1 year 9 months)

Scientist at Novartis (11 months)

EDUCATION

PhD in Biology/ Physics at University of Osnabrück (2011)

Diplom Ingenieur in Biotechnology at Fachhochschule Jena (Diploma thesis at DKFZ)

TELL ME MORE...

What is the function and responsibility of your current role?

As a Clinical Project Manager, I am responsible for organizing and managing all operational aspects of a clinical trial while ensuring adherence to timelines, quality and regulatory requirements. I am responsible for managing project issues such as budgeting, contracting, drug supply, recruitment of patients and study progress, as well as interacting with Contract Research Organizations and other service providers.

What do you enjoy most about the job?

The most enjoyable aspect of working at CureVac in general is being part of a pioneering company that fights for human health with the ambitious goal of making the first mRNA-based drug available to patients in need.
From a project management perspective, the most enjoyable is working in an interdisciplinary and international team.

“Pharma Perspective – CRAs & Clinical Managers”

What are the challenges you face in your job?

The appeal of my work is also a challenge. The management of different parties internally and externally requires a highly flexible and proactive attitude towards changing needs.

What do you think are the general and your personal prospects in this field?

In my opinion the work as a project manager will become more and more complex. For example, less work is outsourced to service providers and the teams working on a clinical trial will become bigger. In addition, the flexibility of adapting your plans to changes that appear in different indications (due to new medications) you are working at is increasingly important.

Are there any specific skillsets or qualifications required for this position?

In general, the position as Clinical Project Manager requires experience in the CRO-, pharmaceutical or biotech industry, with good knowledge of project management skills. It is mandatory to have good verbal and written communication skills, flexibility, and self-initiative. Also, a good understanding of the current national and international laws and guidelines is required.
Having experiences in leading a team (international or national) and cross-functional coordination would be an advantage.

What do you think was the crucial factor for you to get your current job?

In my opinion the crucial factor was having the experience of working in a biotech company, being familiar with flexible structures and the importance a clinical trial has for such a company. This knowledge / experience enabled me to quickly become familiar with CureVac and to support them as a Clinical Project Manager.

Could you recommend any courses, trainings or certificates?

I would recommend to do a general course on project management in clinical trials and to work as a CRA prior being a Project Manager.

Your number one tip or quote?

My number one tip would be to get as much practical experience as possible. Try to get involved either in the management or performance of a clinical study as early as you can in order to gain experience e.g. already during your education.

ADDITIONAL INFO

Profile on dkfz-connect.de Willing to help

DR. CAROLIN BLUME

LinkedIn ✓

Clinical Project Manager

at Fresenius Kabi

SESSION 2: PHARMA PERSPECTIVE – CRAs & CLINICAL MANAGERS

WORK EXPERIENCE

Clinical Project Manager at Fresenius Kabi Deutschland GmbH since April 2015

CRA and Project Manager at Clinical Research Services (03/2009 – 06/2011)

Research Assistant and Tutor/ Demonstrator, Trinity College Dublin (10/2007–12/2007)

EDUCATION

PhD in Natural Sciences at Heidelberg University / DKFZ

MSc in Nutrition Sciences (Biomedicine) at Technical University of Munich

BSc in Ecotrophology at Justus Liebig University, Gießen

TELL ME MORE...

What is the function and responsibility of your current role?

Management of national and international clinical trial projects according to internal, local and international regulations. This entails, e.g.,

- Development of trial concepts with internal and external stakeholders
- Selection and contracting of study sites and contract research organizations (CROs)
- Project planning, implementation, oversight of timelines and budget

What do you enjoy most about the job?

- A great variety of tasks
- Complexity and diversity of study projects
- International setting
- Working with a motivated team

“Pharma Perspective – CRAs & Clinical Managers”

What are the challenges you face in your job?

- A great variety of tasks – and at the beginning, much of it is learning by doing
- Working within an environment of many stakeholders

What do you think are the general and your personal prospects in this field?

Very good.

Are there any specific skillsets or qualifications required for this position?

- Degree in life sciences or medicine (PhD beneficial, but not a must).
- Good problem solving and communication abilities.
- Keeping oversight, but also paying attention to critical details.
- Previous experience in the organization/implementation of clinical trials, e.g., as Clinical Research Associate (CRA) or Project Manager (PM) at a CRO.

What do you think was the crucial factor for you to get your current job?

A combination of a Nutrition Sciences degree, PhD in Biomedicine and experience as a CRA at a CRO.

Could you recommend any courses, trainings or certificates?

In this field, practical experience in a relevant position is the most important.
However, trainings in project management (general/clinical studies) and ICH-GCP may be helpful.

Your number one tip or quote?

Entry into the field of clinical trial management is easiest via a CRO. Don’t hesitate to work your way up from Monitor /CRA I to Senior/Lead CRA and PM – it is an interesting path!

ADDITIONAL INFO

Profile on dkfz-connect.de Willing to help

DR. MELANIE RUPPEL

LinkedIn ✓

Head of Global Submission Services

at Boehringer Ingelheim Pharma GmbH & Co.KG / Global Regulatory Affairs

SESSION 3: DRUG SAFETY & MEDICAL AFFAIRS

WORK EXPERIENCE

Internal Regulatory Affairs Specialist at Boehringer Ingelheim Vetmedica (1 year 8 month)

Postdoctoral Fellow at DKFZ (1 year)

EDUCATION

PhD about Epigenetics in Leukemia at Technische Universität Darmstadt / DKFZ (2009)

Diploma in Genetics, Molecular Biology and Physiology at Technische Universität Darmstadt

TELL ME MORE...

What is the function and responsibility of your current role?

As a global submission manager, I am responsible for steering and coordinating dossier preparation for new marketing authorization applications worldwide. Focus is on electronic common technical document (eCTD) compilation for first wave applications to EU, US, JP and CA, AU/NZ, CH and CA authorities. This means working cross functionally between different groups that provide different parts of the dossier (i.e. nonclinical, clinical, manufacturing/quality and regulatory) on a project management level. And at the same time acting as a translator between the technical Regulatory Operations staff, who prepare the dossier technically and the Regulatory Affairs and Medical staff, who are responsible for the content of the dossier. Regulatory Affairs (RA) in itself and Regulatory Operations (RO) more specifically are constantly evolving fields, since, for example, new formats for electronic dossiers, technologies for electronic submissions or transparency initiatives by health authorities that require input of very diverse data into public data bases, are implemented or changed constantly. Therefore, another aspect of my job is to stay up to date with the changing (electronic) requirements worldwide. Furthermore I train my colleagues in RA and

RO, our RA affiliates, external partners to adhere to these requirements and I also train them on using (new) internal systems, processes etc.

In addition to the above, I have the opportunity to design my own working environment by optimizing or (re)defining our submission processes and taking part in evaluation and testing of software and systems which RA and RO use or will use in the future.

What do you enjoy most about the job?

That no day is like the day before, as internal and external requirements, systems and processes change continuously.

What are the challenges you face in your job?

Same as previous answer ☺

What do you think are the general and your personal prospects in this field?

Regulatory Operations is a tricky field since many of the standard tasks in publishing dossiers are already widely outsourced industry wide and this will likely be extended even more in the coming years. Still expertise knowledge and also project managing skills are required in-house to manage outsourcing partners, but also for the process-related part of the work and for all those extraordinary cases that we are frequently challenged with in Regulatory Operations.

Are there any specific skillsets or qualifications required for this position?

Project management skills, understanding of electronic systems and software used for publishing, archiving etc., understanding of basics in Regulatory Affairs, excellent communication skills.

What do you think was the crucial factor for you to get your current job?

I acquired a basic knowledge of Regulatory Affairs during my first job and was not afraid of the technical aspects of this job. I had a basic idea of eCTDs, and the tools and software required to build them and was confident to fill up the gaps very quickly as I was and am eager to learn new things. Last but not least my communication skills and my self-organizing, team-oriented, diplomatic and independent working style.

Could you recommend any courses, trainings or certificates?

The DGRA course at the University in Bonn. It is a master study, which can be done in parallel to working in a job within one or two years. I did not take it myself, but many of my colleagues did. It provides all the insight into Regulatory Affairs – both from content and technical perspectives.

Your number one tip or quote?

Regulatory Affairs is not only for pharmacists and it proves to be an exciting field to work in although it might not sound like this at first glance.

ADDITIONAL INFO	
Job offers	http://careers.boehringer-ingelheim.com/germany/de

DR. JACEK HAJDA

Head of pharmacovigilance department and scientific project manager

at Coordination Center for Clinical Trials (KKS)

SESSION 3: DRUG SAFETY & MEDICAL AFFAIRS

WORK EXPERIENCE

Head of pharmacovigilance department and scientific project manager at the Coordination Centre for Clinical Trials (KKS) at the University Hospital Heidelberg (11 years)

Human Pharmacologist at Grünenthal GmbH (2 years)

Intern (Assistenzarzt) at the Department of Clinical Pharmacology and Toxicology, University Hospital Zurich (2 years)

Intern (Assistenzarzt) at the Department of Clinical Pharmacology at the Heart-Centre Bad Krozingen (2.5 years)

Intern (Arzt im Praktikum) at the Department of Internal Medicine at St. Vincentius Hospital Karlsruhe (1 year)

EDUCATION

MD at University Heidelberg; Clinical Pharmacology (Board certification)

PhD/MD obtained: November 2001

TELL ME MORE...

What is the function and responsibility of your current role?

Management of safety and tolerability surveillance in clinical trials (pharmacovigilance). Participation in planning, management, analyzing and reporting of clinical trials (scientific project management).

What do you enjoy most about the job?

Diversity of tasks, working within a multi-competence matrix.

“Drug Safety & Medical Affairs”

What are the challenges you face in your job?

Adherence to the complex regulatory requirements, challenging coordination tasks.

What do you think are the general and your personal prospects in this field?

In general high availability of job offers, good prospects at the KKS.

Are there any specific skillsets or qualifications required for this position?

Medical/pharmaceutical and scientific background are recommended.

What do you think was the crucial factor for you to get your current job?

Knowledge of different aspects of clinical research.

Could you recommend any courses, trainings or certificates?

Different training options in pharmacovigilance are available. These are recommendable in parallel with the beginning of work in the field of pharmacovigilance.

Your number one tip or quote?

In pharmaceutical industry pharmacovigilance procedures are not limited to the clinical research but are also applicable to the post-marketing drug surveillance. Due to planned implementations within the European regulatory framework increasing demand for experts may be expected.

DR. NATHALIE FIEGLER

LinkedIn ✓ Xing ✓

Medical Information Manager

at LEO Pharma GmbH

SESSION 3: DRUG SAFETY & MEDICAL AFFAIRS

WORK EXPERIENCE

Medical Information Manager at LEO Pharma GmbH (current)

Clinical Research Associate at Scope International AG (6 month)

Postdoctoral Fellow at DKFZ (5 month)

EDUCATION

PhD in Tumor Immunology at Ruprecht-Karls-Universität Heidelberg / DKFZ (2013)

Master in Cancer Biology at Ruprecht-Karls-Universität Heidelberg

TELL ME MORE...

What is the function and responsibility of your current role?

As a Medical Information Manager, I am the primary contact person for medical enquiries relating to all drugs sold by LEO Pharma in Germany. This includes enquiries from physicians, pharmacists and patients as well as our sales representatives and external agencies. It is my responsibility that our drugs are used in the intended way to ensure drug efficiency and safety.

What do you enjoy most about the job?

I enjoy most that I can interact with a large variety of people every day and that I can really make a difference in the lives of people with serious and chronic diseases. In addition, I deal with a wide variety of different drugs and therapeutic areas.

What are the challenges you face in your job?

One of the major challenges is to provide information that is both helpful and appropriate for the type of enquiry. I have to use a different wording when speaking with a patient

compared to a professor and the type of information I am allowed to share is regulated by different laws for either case.

What do you think are the general and your personal prospects in this field?

Medical Affairs in general is becoming more important because drugs are becoming more complex, thus additional explanation is required to ensure proper drug use. Therefore I think that there will be an increased demand for young professionals with a scientific or medical background in this field in the future.

Are there any specific skillsets or qualifications required for this position?

PhD in Natural Sciences (or Medicine), excellent communication skills, good interpersonal skills, customer-orientation, knowledge in the company's therapeutic areas, ability to prioritize, work in a team and in a regulated environment.

Could you recommend any courses, trainings or certificates?

I don't think that courses will really help you to get a job in this field, since the companies are mostly looking for job experience and not necessarily theoretical knowledge. But I would definitely recommend working on your soft skills (e.g. communication skills, giving presentations, networking). There are many courses and activities for PhD students offered by the DKFZ, which can help you to improve in these areas.

Your number one tip or quote?

When applying in this field, do not focus too much on your detailed scientific knowledge and your PhD project, but on showing your personality and the type of person you are.

ADDITIONAL INFO

Profile on dkfz-connect.de Willing to help

Job offers: www.leo-pharma.de/Startseite/Karriere/Stellenangebote.aspx

DR. SEBASTIAN PIEPERHOFF

LinkedIn ✓ Xing ✓ ResearchGate ✓

Medical Science Liaison Manager

at AstraZeneca GmbH

SESSION 3: DRUG SAFETY & MEDICAL AFFAIRS

WORK EXPERIENCE

Medical Science Liaison Manager at AstraZeneca GmbH

Postdoctoral Fellow, supported by the British Heart Foundation, University of Edinburgh (2 years 4 months)

Postdoctoral Fellow, supported by DFG/DFAIT, University of British Colombia (3 years 1 month)

EDUCATION

PhD in Cardiovascular research at Ruprecht-Karls-Universität Heidelberg / DKFZ (2008)

TELL ME MORE...

What is the function and responsibility of your current role?

I am responsible for the local execution of the medical affairs strategy in my geographical region.

- Medical/scientific communication
- Answering medical/scientific questions from external and internal stakeholders
- Organization of non-promotional symposia or advisory boards
- Teaching scientific content to sales representatives

Attending local and international conferences, write reports

What do you enjoy most about the job?

To “talk science”, I enjoy scientific communication in any form and to attend national and international conferences to keep up to date.

“Drug Safety & Medical Affairs”

What are the challenges you face in your job?

I have the freedom but also the challenge to manage my work load independently. Furthermore my current role involves frequent travelling, mostly in Germany and Europe.

What do you think are the general and your personal prospects in this field?

As marketing in pharmaceutical companies changes along changes in current legal and health economics in Germany, Medical Affairs is and will be even more important in the future. Hence, the future prospects for Medical Science Liaison (MSL) Managers look very good and many companies are currently seeking experienced MSLs.

Are there any specific skillsets or qualifications required for this position?

Transferable skills, such as scientific communication and the ability to quickly learn new disease areas are very important. A proven track record of scientific presentations and publications may help.

What do you think was the crucial factor for you to get your current job?

Because of my proven experience in the field of cardio- and metabolic diseases, together with work experience abroad and skills in scientific communication, I managed to get my first job as an MSL.

Could you recommend any courses, trainings or certificates?

Any trainings and certificates in communication, presentation skills, moderation of meetings will definitely help. English language skills are important for international companies.

Your number one tip or quote?

Focus and be aware of transferable skills learned during PhD and/or Postdoc and don’t highlight academic successes too much, as most of the companies do not like that (my personal experience).

ADDITIONAL INFO

Job offers	http://www.astrazeneca.de/karriere

DR. OLGA UCAR

Medical Writer

at Nucleus Global / Medical Communications

SESSION 3: DRUG SAFETY & MEDICAL AFFAIRS

WORK EXPERIENCE

Postdoctoral fellow at DKFZ (6 years)

PhD (2008) student and postdoctoral fellow at the Max-Planck Institute for Experimental Medicine, Göttingen (7 years)

EDUCATION

Scientific Background: Developmental Biology, Neuroscience, Immunology, Stem Cell Biology

Master in Life Sciences at Georg-August University, Göttingen

TELL ME MORE...

What is the function and responsibility of your current role?

I am part of editorial department, meaning that I help develop all kinds of scientific presentations (abstracts, posters, primary and review manuscripts). Medcomms agencies serve as intermediaries between pharma companies and authors; we ensure that the results of sponsored studies are published according to the authors' wishes and interpretations and that the client adheres to compliance policies.

What do you enjoy most about the job?

I love writing; I have always enjoyed the communications part of academic science much more than the wet lab work. Now I can spend my days writing manuscripts and developing posters and slide presentations, which I thoroughly enjoy. I also like the amount of team work involved and I find the environment much more supportive than it was in academia. The best part is that the agency works in many unrelated areas, so it is guaranteed that I will always be exposed to something new.

“Drug Safety & Medical Affairs”

What are the challenges you face in your job?

The biggest challenge is to keep track of various compliance policies and ensure that they are implemented every step of the way – not so easy when responsible people are unreachable and the deadline is approaching.

What do you think are the general and your personal prospects in this field?

From Medical Writer position, one could rise on the editorial career ladder all the way to Editorial Team Lead, or switch to client services to become Client Services Director. In Nucleus Global there is an additional opportunity of switching to another agency within the group.

Are there any specific skillsets or qualifications required for this position?

Desire (and ability) to write, team work skills, communication skills, attention to detail.

What do you think was the crucial factor for you to get your current job?

I think it was being passionate about writing and communicating science in general.

Your number one tip or quote?

Medcomms is a service industry; it is very client-oriented, and years of academic research experience don’t count for much. If you are not prepared to do boring text checks or secretarial tasks, it’s probably not for you.

ADDITIONAL INFO

Profile on dkfz-connect.de Willing to help

Job offers: www.nucleus-global.com

Clinical Research - Useful Resources

We hope you found the Career Day useful in expanding your knowledge on clinical research and possible career paths. On this page, you will find a number of links (some recommended by our speakers) that might be useful for you.

General and clinical trials

- Comprehensive and technical resources from the FDA on the drug approval process. www.fda.gov/Drugs/DevelopmentApprovalProcess

- Mibeg-Institut Medizin clinical monitoring course (recommended by Dr. Natoli). www.mibeg.de/medizin/klinischer-monitor/

- A collection of articles written by Dr. Vera Madzarevic, a Canadian senior director of clinical trials. They provide advice on how to obtain CRA experience and transit into clinical research. In addition, there is information on global trends and a future outlook on the field of clinical research. (LinkedIn membership required to access the articles). www.linkedin.com/today/author

- "Biopharmaceutical Research & Development: The Process Behind New Medicines": overview of the drug development process, published by PhRMA (the Pharmaceutical Research and Manufacturers of America), which represents the major biopharmaceutical and biotechnology companies of the US. www.phrma.org

Medical affairs

- A nice overview of the role and function of the medical affairs department, and further specializations within the field. www.bioprocessintl.com/analytical

Regulatory affairs and pharmacovigilance

- German Society for Regulatory Affairs. The network of regulatory affairs professionals based in Germany. Includes information for continued education (recommended by Dr. Ruppel), regulatory job offers and internships in Germany, workshops and conference opportunities for members. http://dgra.de/

- European Medicines Agency (EMA), comprehensive and technical resources of regulatory information. www.ema.europa.eu/ema/index

- Feature on Regulatory Affairs, Science Careers. While old (the articles were published back in 2003), this feature contains many valuable insights into the RA field, its requirements and transitional stories. www.sciencemag.org/careers/2003/11/

DKFZ PhD Student Council

The PhD Student Council 2015/2016 members (front: Azer, Juliane, Sara; back: Antonino, Sebastian, Mahak)

There are over 600 German and international PhD students who work at the DKFZ in Heidelberg. From amongst them, six people are annually elected to form the PhD Student Council. The members of the Council serve as representatives of the student body, coordinate scientific and non-scientific student life in various ways and foster exchange and networking between PhD students. The PhD Teams are an integral part. One in ten PhD students volunteers to help in one of the teams, which are coordinated by the Student Council.

One of our aims is to make PhD life better for all students. An important part of this task is organising social events as an escape from the daily routine, where you can meet your peers and colleagues, make friends, exchange experiences and expertise or simply relax for a bit. The PhD Happy Hours, for example, are an excellent opportunity to get in touch not just with other PhD students, but also postdocs and master students in a relaxed and enjoyable atmosphere to discuss science and everything else. In addition, the Social Events Team and Party Team plan and organise movie nights, sports tournaments, two walks in spring and autumn and several parties around the year.

This year, the PhD Student Council worked hard to extend its repertoire. Some of our new formats include the 'Meet & Greet' in which you can meet experienced individuals from both academia & industry to learn about their journey and ask them questions in a relaxed environment.

Another one is the 'Welcome Lunch' which takes place once every month and is aimed at integrating the new PhD students to the DKFZ community as soon as possible. Furthermore, we established connections between people with shared interests and supported hobby clubs. You want to play chess, act in a play or practice martial arts, and are looking for others who want to join you? You can almost certainly find someone who is just as enthusiastic about your hobby right here at the DKFZ!

Besides creating networks and providing opportunities to forge social connections, we also have some other tasks. The Welcome Team makes the two PhD selection rounds per year as pleasant and informative for the applicants as possible, and provides further help for newcomers once they have joined the DKFZ. The Retreat Team organizes the two PhD Retreats that take place in Weil der Stadt each year. Both these teams cooperate closely with the Graduate Office. Together with other teams from various different institutes in Heidelberg, the Conference Team helps to organize the Heidelberg Forum for Young Life Scientists. The Communication Team keeps the website updated, conducts an annual survey among the PhD students and keeps everyone updated on upcoming events.

Finally, the Student Council also serves as a liaison between the PhD students and the DKFZ Management Board, and represents your interests on a Helmholtz-wide level in the Helmholtz Juniors.

If you want to learn more and stay informed, have any questions, or wish to help, do not hesitate to contact us or check out our Facebook page:

Phd-student-council@dkfz.de

www.facebook.co/groups/DKFZphd/

The PostDoc Network –

from PostDocs for PostDocs

OUR MISSION

The **PostDoc Network (PDN)** was formed to represent the PostDocs` interests and to achieve the **best conditions for career perspectives and scientific output**. Our main goals are to raise the **visibility of PostDocs** in and outside the DKFZ, to support **career development** and to increase **social and scientific networking** among PostDocs.

Newsletter

VISIBILITY

Our **website and mailing list** provide general information about the PDN and offer a platform for PostDocs to communicate with each other and to discuss issues important to them.
The quarterly **Newsletter** contains information about upcoming events and personal accounts of PostDoc experiences at DKFZ.

Career Develop-ment

Alumni Network

CAREER DEVELOPMENT

In collaboration with the DKFZ Advanced Training Center, the PDN organises **seminars and workshops** tailored for PostDocs` needs, as well as **Career Days** where invited speakers provide expert perspectives on how to pursue careers in industry, academia and elsewhere. **Alumni** and current DKFZ researchers are invited to share their personal career paths. The participants are given ample time to join round table discussions and to network with invited guests.

PDN Network

dkfz. GERMAN CANCER RESEARCH CENTER IN THE HELMHOLTZ ASSOCIATION

50 Years – Research for A Life Without Cancer

Get Together

PostDoc Network

NETWORKING

The annual **Retreat** aims to encourage scientific and social interactions between PostDocs, in order to improve the research and personal experience of scientists.

The monthly **Lunch Talk Series** was started by the PDN and the BioMed X Innovation Center to provide a platform for intellectual exchange between researchers working in diverse fields of life science research in Heidelberg.

The soon to start "**Research Lounge – let's talk science**" will encourage scientific collaboration and discussion within the DKFZ. At monthly **Get-Together events** PostDocs can get useful information about life in Heidelberg and work at the DKFZ.

Expertise Exchange

PostDoc Retreat

Find more information on PDN activities on our official website: www.dkfz.de/en/postdoc-network/

To be up-to-date with current and upcoming events join our mailing list: pdn@dkfz.de

PDN Committee 2015 © PDN

DKFZ Career Service

Scientific Life beyond the lab

www.dkfz.de/careers

Career Counseling

- Career Guidance
- CV and Cover Letter Review
- Personal Appointments careeradvice.youcanbook.me
  Tue/Thu in TP4; Wed/Fri in Main Building

Information & Training

- Career Info Events (Career Days, Career Coffee/Lunch, ...)
- Seminars/Trainings (Job Applications/Interviews, Business Skills, ...)
- Heidelberg Science Career Calendar tinyurl.com/5wuerfx

Networking

- Platform: dkfz-connect.de for current and former DKFZ scientists
- Group: linkedin.com/groups/DKFZ-Career-Network-4831669
- Page: facebook.com/phdcareers

We support YOU in taking the next step in YOUR Career!

Dr. Barbara Janssens: Manager since 2011: She is Belgian (PhD in molecular and cell biology from Ghent University), and after a postdoc in Paris she worked for five years as an Editor at Wiley-Blackwell.

Marion Gürth: Project Coordinator since 2013 studied Biology at the TU Darmstadt and did her Diploma in Heidelberg in 2005. Marion supports all projects and focuses on building up the DKFZ Career Network.

Contact
Email: careers@dkfz.de
Phone: +49 6221 42-2146 and 1762
Office: DKFZ main building (8th floor, east) H828 and H832

New Office !

DKFZ Career Service – Mentoring: Useful Tips

What is a Mentor? What is a Mentee? What is Mentorship?

A **mentor** is a coach, guide, tutor, facilitator, counselor and trusted advisor. A mentor is someone willing to spend his or her time and expertise to guide the development of another person.

A **mentee** is a student, protégé, apprentice and eager learner. A mentee is someone who wants to learn from someone who knows and seeks their valuable advice in order to grow personally and/or professionally.

A **mentorship** is a relationship formed between a mentor and mentee with the goal of sharing knowledge and expertise between the mentor and the mentee. It can be a formal relationship with written goals and scheduled meeting times or it can be as informal as an occasional chat or email exchange.

(Source www.mentorscout.com)

Mentors are not necessarily much more senior than mentees. You can just as well be a

a. **Peer Mentor** = someone about or close to your own career stage (e.g. Postdoc for a PhD student/Postdoc)

b. **Senior Mentor** = someone with professional experience useful for your career interests

Mentoring Options

10MM: 10 Min Mentoring	Tandem Mentoring
• Mentee prepares specific questions • Mentor introduces area & limits of expertise, vision/approach • Briefly discuss possible SMART goals and how the mentor can contribute • Decide (when to make) a follow-up "tandem" appointment • Give Feedback	• 2-4 meetings of 1-2h over 1-2 years Peer Mentor = close to your own career Senior Mentor = professional experience • Set SMART goals • Talk WITH but also ABOUT each other • End with feedback meeting – after agreed time/agreed goal reached – when either partner wants to
The 5 BASIC Questions 1. What do you do? 2. How did you get into it? 3. What is good? 4. What could be different? 5. Who else can tell me more?	**SMART Goals** **S**pecific **M**easurable **A**ctive **R**easonable **T**ime-bound

Find more information, guidelines and possible mentors on www.dkfz-connect.de !

DKFZ Alumni Association

GERMAN CANCER RESEARCH CENTER ALUMNI

The Alumni Association strongly supports the maintenance of long-lasting personal and scientific relationships between present and former members of DKFZ. It aims to stimulate the exchange of ideas and experiences in the ever-growing DKFZ family, nationally and internationally. Particularly important target groups are young scientists, especially those from abroad that are currently (or previously) working at the DKFZ.

Alumni members benefit from an attractive range of activities:

Alumni visiting the European Parliament in Strasbourg

- Publication of a Newsletter reporting on recent developments and future plans.
- A biannual scientific meeting at the DKFZ, as well as meet-up events e.g. during the AACR meeting or at Career Fairs.
- Supportive social and cultural activities for visiting scientists and members of the DKFZ.
- A travel grant program for short-term visits of young scientist to the DKFZ.
- The local Alumni Club Heidelberg organizes regular meetings, lectures and excursions to Heidelberg and nearby destinations of scientific, cultural or political interest.
- Possibility to get an alias name@alumni.dkfz.de forwarded to your private email.

Contact among members is supported by the password-protected membership directory. The membership fee is voluntary (but sponsors are welcome).
Current and former DKFZ colleagues are welcome to join. Please register at:
www.dkfz.de/alumni

DKFZ just launched a new platform for current and former DKFZ employees: www.dkfz-connect.de already features over 1200 profiles from all over the world, and includes jobs, mentoring, news and much more. It would be great if you could join, too.

Contact information

- Prof. Dr. Manfred Schwab (Chairman of the Board of Alumni DKFZ)
  e-mail: m.schwab@dkfz.de
- Susanne Schunk (Management Alumni DKFZ)
  e-mail: susanne.schunk@dkfz.de, phone: +49 (0)6221-424499

Translational Research at DKFZ, NCT and DKTK

The National Center for Tumor Diseases (NCT) Heidelberg

The NCT is a joint institution of the DKFZ, Heidelberg University Hospital and German Cancer Aid. The NCT's goal is to link promising approaches from cancer research with patient care from diagnosis to treatment, aftercare and prevention. The interdisciplinary tumor outpatient clinic is the central element of the NCT. Here the patients benefit from an individual treatment plan prepared in a timely manner in interdisciplinary expert rounds, the so-called tumor boards. Participation in clinical studies provides access to innovative therapies. The NCT thereby acts as a pioneering platform that translates novel research results from the laboratory into clinical practice. The NCT cooperates with self-help groups and supports them in their work.

DKTK - The German Cancer Consortium

Physicians and cancer researchers need to work closely together if patients are to benefit from successful cancer research. DKTK forms a strong, long-term, institutional structure between the DKFZ, the NCT and seven university-based Comprehensive Cancer Centers across Germany. The aim is to accelerate the translation of new diagnostics and treatment approaches into clinical applications.

DKTK - Personalized cancer treatment for every patient

Modern genome analyses, genetic activity profiles and protein structure analyses reveal the minuscule protein differences between tumor cells and healthy cells which, when taken together, can lead to malignant forms of cancer. A key focus of the consortium's work is on using these technologies to investigate how results from basic research can be used for personalized therapies, so as to recommend the most promising course of treatment for every patient. In addition, unique research platforms are made accessible to all DKTK sites. The aim is to harmonize methodologies and to implement compatible IT solutions to ensure comparable data at all partner sites.

DKTK - Translating successful cancer research into clinical practice

DKTK provides a strong stimulus for activities in translational oncology at DKFZ. Numerous novel clinical studies have been instigated and coordinated by DKTK scientists. Notable examples include an investigator registry for children with relapsed or refractory high-risk tumors (INFORM), as well as clinical studies investigating the potential of new biomarkers for the prognosis of patients with tumors of the esophagus (MEMORI) and options for radiochemotherapy in head and neck tumors (HNprädBio).

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PPD is a worldwide community of professionals committed to helping our clients deliver life-changing therapies.

Our industry-leading scientific, medical and strategic minds design, plan and implement high-quality, full-scale global programs from early development to post-approval, including laboratory services, to help clients reach key milestones on time and on budget.

Our medical experts develop and provide counsel on feasibility and protocol optimization across a range of therapeutic areas to drive patient and site enrollment. PPD leverages science, technology and data to engage sites and patients and bring the trial closer to the patient, while relentlessly exploring new and innovative approaches in this area.

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FOR **48** OF TOP **50** pharmaceutical companies[1]
AND **750+** biotechnology companies

INVOLVED IN DEVELOPMENT OF
31 OF THE **68** therapies approved in 2015 BY THE FDA[2]

Early Development Services Expertise and infrastructure to deliver customized early phase strategies

- Comprehensive Phase I clinical trial services
- Broad translational medicine capabilities and pharmacodynamics expertise
- Experience creating biomarker strategies and developing assays
- Extensive network of clinical pharmacology sites

Clinical Development Services

Comprehensive product development services

- Full-service Phase II-IIIb clinical studies for multinational regulatory submissions
- Proven expertise in biostatistics and data management, clinical supplies, medical communications, regulatory affairs, pharmacovigilance, and site intelligence and activation
- Real-time data and analysis delivered by Preclarus®—driving faster and more informed decision-making and saving valuable time and money

PPD® Laboratories Services Global lab services—spanning small and large molecules

- Bioanalytical lab
- GMP lab
- Central lab
- Vaccine sciences lab
- Biomarker services

Post-approval Services Real-world research services to optimize the life cycle of a product

- Epidemiology, health economics and outcomes research, post-approval safety studies, registries, observational research, retrospective database analysis, expanded access/compassionate use, extended access, REMS, patient-reported outcomes and pragmatic trials
- Alliance with HealthCore, providing large amounts of claims data and electronic health records to assess more quickly how products perform in a real-world setting

Consulting Services Diverse expertise across therapeutic areas and functional disciplines

- Product development
- Biosimilars
- Adaptive trial design
- Pediatrics
- Rare diseases
- Cardiovascular outcomes
- Medical devices

1 Based on 2015 R&D spend as reported by EvaluatePharma
2 PPD analysis of FDA data

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We're Listening

YOUR FEEDBACK is important for us!

Please answer a few questions at:

www.surveymonkey.de/r/MXXX5FZ

Contact us: Careerday@dkfz.de

Save the Date – Upcoming Career Days

Organizers

The organizers of the Career Day take part in a 'hands-on Project Management' training offered by the DKFZ Advanced Training department and are supported by the Career Day Steering Committee.

Team Speakers

From left to right:

Ramon Lopez Perez
Krishna Das
Gözde Bekki
Ann-Christin Gaupel
Anna-Lisa Böttcher
Ahmad Zia Shams

Team Marketing

From left to right:

Eva-Maria Ewen
Horace Chan
Lea Schroeder
Lena Herbst
Adriane Gardyan
(not in the picture)

Project Coordinator

Lisa Schardt

Steering Committee

Dr. Barbara Janssens
DKFZ Career Service

Dr. Celina Cziepluch
DKFZ Advanced Training

Dr. Timo Kehl
DKFZ Biosafety

Marion Gürth
DKFZ Career Service

Thank You

The organizing team of the Career Day

"CLINICAL RESEARCH"

says

THANK YOU

to everyone who helped us to make this day a success…

… thanks to the Management Board of DKFZ and the Career Day Steering Committee for all their support.

… thanks to Dr. Andreas Eisenmenger for giving his valuable time for organizing the workshop.

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08:00 **On-site Registration**

09:00 **Session I: "From Translational Research to Clinical Research"**

Prof. Klaus Kopka (DKTK) & Prof. Frederik Giesel (DKTK)

Dr. Claudia Trierweiler (NCT, Project Manager)

10:00 **Coffee Break**

10:30 **Session II: "Pharma Perspective – CRAs & Clinical Managers"**

Dr. Antonino Natoli (Quintiles, Senior CRA, Frankfurt)

Dr. Alberto Calabrò (Roche, Global Compassionate Use Coordinator, Basel)

Agata Bloswick (Quintiles, Clinical Program Director, Krakow)

Dr. Sven Grösgen (Roche, Clinical Operations Study Manager, Mannheim)

11.30 **Lunch Break**

12:50 **Session II (continued)**

Dr. Sabine Brutlach (CureVac AG, Clinical Project Manager, Tübingen)

Dr. Carolin Blume (Fresenius KABI, Clinical Project Manager, Bad Homburg)

13:20 **Panel Discussion with Speakers**

14:00 **Round Table Discussions with Speakers (Coffee Break)**

14:30 **Open Discussions / Networking**

14:50 **Session III: "Drug Safety & Medical Affairs"**

Dr. Melanie Ruppel (Boehringer Ingelheim, Head of Global Submission Services, Ingelheim)

Dr. Jacek Hajda (KKS, Head of Pharmacovigilance and Scientific Project Manager, Heidelberg)

Dr. Nathalie Fiegler (Leo Pharma, Medical Information Manager, Frankfurt Area)

Dr. Sebastian Pieperhoff (AstraZeneca, Medical Science Liaison Manager, Mainz)

Dr. Olga Ucar (MediTech Media, Medical Writer, Manchester)

16:00 **Round Table Discussions with Speakers (Coffee Break)**

16:50 **Closing Remarks - Announcements**

17:00 **Reception: Open Discussions / Networking**