CV Karin Jorga, PhD

Professional Experience

KarinJorga Life Science Consulting 08/2014 -
Founder and CEO, Basel, Switzerland

- Specialized consultant for development of healthcare innovations. Focus on Due Diligence Assessments for investors and clinical pharmacology expert advice for Pharma and Biotech companies from entry-into human enabling studies to clinical proof-of-concept and full registration. Special expertise in Phase 1, PKPD, modeling and simulation strategy and pediatric drug development.

03/2013 - 07/2014

Strategic Advisor Roche Pharma Research & Early Development
Pharma Research & Early Development (pRED), Roche Innovation Center Basel, Switzerland

- Executive Leader for Divestiture of Cardiovascular/Metabolic Portfolio under the governance of the Roche Corporate Executive Committee (John C. Reed and Sophie Kornowski-Bonet)
  - Lead the departmental activities to support the successful out-licensing of assets from the portfolio after Roche's strategic decision to exit the cardiovascular/metabolic field.
  - In collaboration with Pharma Partnering develop and implement out-licensing strategies to efficiently partner the assets with optimal financial return on investment while minimizing the continued resource requirements.
- Scientific lead for several Scientific Incubator Cooperations under the Roche Pharma Partnering initiative: "Expanding the Innovation Network (EIN)"
  - Represent Roche on the Joint Steering Committees with Bio-X (Uppsala, Sweden), Unitectra (Switzerland) and PBBR (UCSF, San Francisco, CA).
  - Identify Breakthrough Discoveries from academic institutions and small biotech companies.
    - Lead feasibility assessments of business and project plans.
    - Decide project selection and budget allocation.
    - Guide on informative proof-of-concept and realistic exit strategies.
- Strategic Advisor Pharmaceutical Sciences
  - Support the Global Head of Pharmaceutical Sciences (Thomas Singer) in the development and implementation of the strategic agenda for Non-Clinical Safety and Translational Research Science with focus on biomarkers, diagnostic co-development and Personalized Healthcare.
  - Assess external innovation opportunities including development of a Virtual R&D Model for faster to Clinical Proof-of-Concept for highly innovative products.

04/2011-02/2013

Global Head Biomarker Science and Technology
Pharma Research & Early Development, Roche, Basel, Switzerland

- Promoted to Global Head Biomarker Science and Technology to lead the department responsible for state-of-the art biomarker strategies including technologies such as Genetics/Genomics, Proteomics, Tissue Biomarkers and Imaging across all therapeutic areas (Virology, Oncology, CNS, Metabolism, and Inflammation).

- Implemented functional framework to apply Biomarker Science and Technologies to deepen the understanding of diseases leading to the identification of new drug targets, disease biomarkers and Personalized Healthcare (PHC) solutions.
- Major responsibilities included:
  - Scientific and strategic input into biomarker programs/PHC strategies from early discovery to proof-of-concept.
  - Managing the Biomarker Technology and Science Department (approx. 100 employees).
  - Project prioritization according to R&D strategy (Budget and Resources).
  - Member of the Translational Science Leadership Team and responsible for the Roche Pharma Research and Early Development Biomarker Vision and Strategy.

06/2010-03/2011

Vice President Translational Medicine Virology
Pharma Research & Early Development, Roche, Nutley, NJ

- Stepped in to lead the Department of Translational Medicine Virology on short notice and ad interim until a permanent VP was found.
- Provided scientific and business leadership to Virology Early Development and Translational Medicine.
- Major Responsibilities included:
  - Accountable for development and implementation of successful development strategies that lead to early Proof-of-Concept and successful NDA.
  - Chair of the Development Review Committee for Virology.
  - Chair of several strategic alliances with partner companies.
  - Member of the Disease Area Portfolio Committee responsible for development and implementation of the Company R&D strategy for Virology.
  - Member of the Strategic Portfolio Committee.

01/2010-03/2011

Vice President 'In Silico' Biology
Department of Translational Research Science, Pharma Research & Early Development, Roche, Nutley, NJ

- Transitioned back to Roche Pharma R&D in the US to build up In Silico capabilities as part of the newly formed Global Department of Translational Research Science.
- Consolidated the major In Silico activities including Bioinformatics/Biostatistics, pre-clinical and clinical Modeling and Simulation across all Therapeutic Areas (Virology, Oncology, CNS, Metabolism, and Inflammation) into one strong group to drive the integrated application of Systems Biology.
- Collaborated closely with the data generating functions of Translational Research Science (Genetics/Genomics, Pathology, Imaging and Proteomics) to drive the development and implementation of biomarker and 'In Silico' strategies with the aim to support identification of new drug targets and disease biomarkers and enable model-based drug discovery and development.
- Major responsibilities included:
  - Managing In Silico Area Analysis Heads and chairing the In Silico Leadership Team.
  - Manage Project Prioritization according to R&D strategy.
  - Member of the Translational Science Leadership Team, Non-Clinical Drug Safety Committee and Development Review Committees for Virology, Inflammation and Oncology.

2008-2009

International Assignment as Functional Excellence Liaison at Genentech Inc.

Department of Development Science, Genentech Inc., San Francisco, USA

- Transferred from Roche headquarters in Basel to Genentech in San Francisco to gain leadership experience and complementary technical knowledge in a completely different and independent setting.
- Guided the Clinical Pharmacology programs of the small molecule portfolio as Scientific Advisor and reinforced the development of functional excellence for Clinical Pharmacology of small molecules and Modeling & Simulation (presentations, guidance and strategic documents).
- Increased the scientific impact of Development Science through active participation in Development Review Committees and Development Science Review Committees.
- Participated in various functional initiatives to strengthen the departments' early development capabilities and to increase the probability of project success through clinical Proof-of-Concept.

2004-2008

Global Head Clinical Pharmacology

Clinical Research and Exploratory Development, Roche, Basel

- Promoted to Global Head of Clinical Pharmacology to lead the turnaround and further build-up of the department at Roche: Two groups representing Clinical Pharmacology Science (70 people) and Clinical Pharmacology Operations (80 people) were combined and re-aligned into one efficient department. In 2007 Data Management was also included, leading to 220 people across 4 sites (Basel, Welwyn, Nutley and Palo Alto).
- The vision for Clinical Pharmacology was to utilize translational medicine, biomarker science and Modeling & Simulation to inform decision making and advance the most promising new drug candidates efficiently and successfully through the value chain.
- The driver of the re-alignment was to shorten Phase 1 cycle times and to improve the overall quality of the Clinical Pharmacology input into projects across the therapeutic areas. All key processes were evaluated and re-designed if needed, leading to changes on roles and responsibilities, best practices and reporting lines.
- Major Responsibilities of the Global Head of Clinical Pharmacology also included:
  - Scientific and strategic input into Clinical Pharmacology programs from pre-clinical and clinical up to lifecycle management.
  - Operational responsibility for Clinical Pharmacology studies executed either in in-house Clinical Pharmacology Units or external CROs.
  - Budget and resource planning.
  - Member of the Pharma Clinical Research and Exploratory Development Management Team. Member of the Non-Clinical Drug Safety Committee.

2002-2004

Global Head Modeling and Simulation

Clinical Pharmacology, Roche, Basel

- Returned to Clinical Pharmacology to successfully start-up a Global Modeling and Simulation Group for Roche: The challenge was to promote the value of this new technology, build up the group and simultaneously deliver convincing results.
- Led and managed a global group of up to 12 people specialized on Modeling and Simulation of clinical data.

- Provided strategic input into Modeling and Simulation activities for projects from pre-clinical and clinical up to lifecycle management and chaired of the cross-functional Modeling and Simulation Network in R&D at Roche.

2001-2002

Project Leader Exploratory Development
Exploratory Development, Roche, Basel

- Transitioned from Scientific Expert to Matrix Leader to gain broader drug development expertise beyond Clinical Pharmacology and strengthen leadership competencies.
- Led a cross-functional project team of 12 to 15 people with the focus of transitioning early projects from Late Stage Discovery to the Proof-of-Concept Stage.
- Ensured effective project management and project planning.
- Collaborated with Pharma Licensing and coordinated R&D teams for Due Diligence assessments of several licensing candidates.

Pharmacokineticist/Clinical Pharmacologist 1991-2000
Clinical Pharmacology, Roche, Basel

- Entered into Pharmaceutical Industry as Scientific Expert and took the very first project (COMT inhibitor in Parkinson's Disease) as Clinical Pharmacologist from entry-into-human (EIH) to regulatory approval (NDA).
- Planned and executed global clinical pharmacology programs for development candidates as part of the overall drug development plans.
- Led a clinical pharmacology team of up to 6 people.
- Represented clinical pharmacology aspects in internal teams and external discussions with regulatory authorities, scientific advisors and conferences.
- Compiled pertinent data for the Expert Report and Clinical Summaries for the NDA.
- Provided scientific support of marketing activities, including presentation of pharmacological data at national and international conferences. Strategic input into the Lifecycle management of the product.

Education

1990-1991	**Post doctoral Fellow** University of Kentucky, Lexington, US
1987-1990	**PhD Pharmaceutical Science** Borstel Research Institute, Borstel, Germany: "Model of Action and Antimycobacterial Activity of 4-(4'-Aminophenylsulfonyl) benzoic acid esters. Derivation of Quantitative Structure-Activity-Relationships"
1982-1987	**Master of Science** Pharmaceutical Sciences, Christian-Albrechts-University, Kiel, Germany
Languages	English and German - fluent