

Curriculum Vitae

1. Name:

Oliver Bohnsack, M.D., Ph.D., MBA

2. Job Title:

Vice President
Head of Oncology
Scientific and Medical Services, Medical Imaging

3. Summary of Experience:

Global Head of Oncology	since 2009
Vice President Scientific and Medical Affairs	since 2018
Senior Director Medical Affairs	2009 – 2018
Medical Director	2006 – 2009
Associate Medical Director	2004 – 2006
Director, Strategic Development	2003 – 2004

Vice President Scientific and Medical Affairs Medical Imaging in Berlin, Germany.

In this role he serves as Head of Oncology.

As Global Head of Oncology his office is in Berlin Germany and as a Board certified Radiologist he has training and background in both Germany and the U.S.A. Throughout his career with Calyx since now nearly 18 years he medically and scientifically led and managed the imaging components of more than 600 clinical trials. He has developed equally as many imaging charters for various indications and complexities and thus far supported with his contributions the approval of 24 oncology medications. Dr. Bohnsack regularly presents at international conferences and publishes on Imaging in Clinical Trials, especially regarding the use of standardized review criteria and imaging based endpoints with a more recent focus on immune-oncology. He is co-author of the immune-related response criteria (irRC, 2009) and first author of irRECIST (2014), co-author of Comparison of assessments using RECIST and irRECIST by Eggleton P. et al. (2020).

His Masters in Business Administration in Health Care Management is from the University of California, Irvine and his Ph.D. in Radiology in Computer Tomography Radiation Modulation and Reduction is from the University of Munich.

4. Therapeutic area of Expertise:

Strong experience in Oncology by medically and scientifically designing, leading and managing the imaging component of clinical trials, developing numerous protocols and imaging charters with various indications and various complexities, in phase I, II and III, with and without regulatory submission. Scientific advisor, consultant and Steering Committee member. Co-author of the irRC criteria (Wolchok), author of irRECIST, co-author of Comparison of Assessments Using RECIST and irRECIST.

Indication	Phase Clinical phase of the study	Time on the Project Time you personally were involved in the project.	Countries List only those countries (not regions) where you were directly involved / accountable.	Services Involved The capacity in which you worked on the trial/your role on the study.
All Oncology indications that require central imaging	I - III	n/a	n/a, globally	Scientific Lead Medical Imaging

5. Professional Experience:

Consultant

Covidence, Eschborn (Frankfurt), Germany
2003

Marketing strategies for business expansion into the United States. Marketing and Commercial analysis. Business Development in North America. Internal business competencies analysis. Competitor analysis and differentiation strategies. Representation at various exhibitions and conventions. Corporate social event organization and execution. Training in ICH GCP, monitoring requirements, Selligent® CRM Software.

Manager for Training & Education

Siemens Medical Solutions, Forchheim, Germany
2001 – 2003

Develop training and education concepts for customer education and training for radiologists and technologists. Planning and execution of customer focused education with clinical cooperation partners. Internal training and employee education. Customer retentions marketing. Logistical planning and management of training centers. Development and implementation of new media training tools. Change management with restructuring of customer service hotline support. Expand and realign clinical marketing. 1.8 M Euro budget responsibility.

Product Manager, Advanced Radiology, Multislice Computed Tomography

Siemens Medical Solutions, Forchheim, Germany
2001

Product Strategy for helical CT Scanners:
New Product Launch and Campaign
Product Termination and Transition
Clinical and Applications Marketing
Product Sales Support
Customer Support
Internal and External Training
Product Internet and Intranet Content Management

Independent Entrepreneurial Investment and Consulting
Facilitate Business Start-Up Evaluation
Explore Entrepreneurial and New Venture Investment Opportunities

Clinical Research Specialist for Patient Recruitment into Clinical Trials
Healthcare Communications Group, Hawthorne, CA
2000

Providing medical knowledge in combination with business management and IT skills. Create, acquire, and execute complex patient data with presentations. Develop Marketing Strategies to target clients and candidates. Conceive Promotional Materials that improve brand recognition. Produce new business leads and opportunities through solution selling. Foster business relations with community at large. Contribute to enhancement of internet presence, web page design. Protocol development and review for marketing campaign. Interact and communicate with CRO and Research Site routinely. Develop and execute study campaign design. Research, develop and write briefs and abstracts.

Intern, Department of Health Services, Quality Improvement
Maxicare HMO, Los Angeles, CA
1999

Developed HMO membership questionnaire, including data mining and data base co-development for nation wide application. Analyzed data and presented findings to medical advisory committee for strategic planning. Contributed medical expertise and quality assurance to management teams.

Operations Manager
R. Meadors & Assoc., Inc., Manhattan Beach, CA
1998 – 1999

Project manager for a mid-size general contractor/architect/development firm overseeing payroll, accounting, scheduling, vendor relations and personnel management. Assisted in business turn around and organization of office operations to the point of replacing position with administrative staff. Improved productivity through database development of resources, billing and project management.

General Manager, Medical Director and Co-Founder
KD Fleskes Ambulance and Rescue Services, Muelheim, Germany
1993 – 1996

Privately operated ambulance and rescue service. Emergency Physician. Also responsible for New Business Development, Marketing, Customer Relations, Scheduling, Staff Supervision, and Training. Developed case tracking database. Implemented electronic billing operations.

6. Education

Resident, then Fellow in Diagnostic Radiology
various hospitals and private practices in Germany and Austria
1989 – 1998

Medical University Essen, Germany, graduation with approbation 1989

M.D. Medical University Essen Germany
MBA in Health Care Management, University of California, Irvine U.S.A.
Ph.D. in Radiology in Computer Tomography Radiation Modulation and Reduction, University
Munich Germany

7. Language Skills:

German
English

8. Professional Associations:

ASCO, ESMO

9. PUBLICATIONS:

Manitz J, Eggleton SP, Bohnsack O, et al., Comparison of tumor assessments using RECIST 1.1 and irRECIST, and association with overall survival, Journal for ImmunoTherapy of Cancer (JITC) 2/2022

Narang J, Caplan C, Bohnsack O, et al., Bruton tyrosine kinase inhibitors (BTKi) therapies in chronic lymphocytic leukemia (CLL): Review of multiple trials data for incidence of lymphocytosis and designation of partial response with lymphocytosis (PRL), online poster at ASCO 2021

Bajpai S, Sharma M, Bohnsack O, et al., Imaging determinants of early progression in relapsed and refractory Hodgkin and diffuse large B cell lymphoma, Journal of Clinical Oncology 2021

Sharma M, Bohnsack O, Singareddy A, Lung Cancer: How likely is baseline tumor burden related to time to disease progression, poster at ECR 2021

Bohnsack O, Narang J, Lencioni R, et al. Response assessment in advanced hepatocellular carcinoma - What is the best criteria to utilize? mRECIST or RECIST 1.1 - A retrospective meta-analysis of multiple phase III trials, poster at ESMO Asia 11/2020

- Sharma M, Bohnsack O, Singareddy A, Reliability of mRECIST criteria for HCC in the relationship between response and progression, Journal of Clinical Oncology 2020 38:15_suppl, e16645-e16645, ASCO 2020
- Manitz J, Eggleton SP, Bohnsack O, et al., Comparison of assessments using RECIST 1.1 and irRECIST, and association with overall survival in 1,765 patients with advanced solid tumors treated with avelumab monotherapy, oral presentation at IO360 in 2020
- Manitz J, Eggleton SP, Bohnsack O, et al., Association between response assessments using RECIST and irRECIST in 1,765 patients with advanced solid tumors treated with avelumab monotherapy, poster at SITC 11/2019
- Sharma M, Bohnsack O, Singareddy A, Identification of new lesion with disease progression in Ovarian cancer per RECIST 1.1, Journal of Clinical Oncology 2020 38:15_suppl, e18058-e18058, ASCO 2020
- Sharma M, Bohnsack O, Clarc D, Metastatic new disease in ovarian cancer: organ location and impact, poster at ECR 2019
- Sharma M, O'Connor M, Bohnsack O, et al. Reader Disagreement Index: A better indicator for monitoring reviewer discordance, poster at CSCO 2019
- Sharma M, Bohnsack O, O'Connor M, et al. RDI as a method for reviewer performance monitoring in BICR setup for improving data quality, Journal of Clinical Oncology 2019 37:15_suppl, e18082-e18082, ASCO 2019
- Sharma M, Bohnsack O, Clarc D, Impact and influence of PET on imaging related endpoints in patients with Lymphoma using IWG-NHL or Lugano classification, Journal of Clinical Oncology 2019 37:15_suppl, e19061-e19061, ASCO 2019
- Devashanam A, Bohnsack O, Fotinos-Hoyer K, Bennet D, McMahon M, Enus N, Assessing prostate cancer on imaging in clinical trials, A Summary of Recommendations from PAREXEL Informatics, Patient Technology Solutions, Medical Imaging, White Paper, PAREXEL 2018
- Bohnsack O, Scientific and Medical Support for Managing Central Imaging in Oncology Trials, presentation at IO360, 2018
- Bohnsack O, Operational Aspects Of Independent Reviews for Immune-Oncology Clinical Endpoints presentation at IO360, 2018
- Sharma M, Bohnsack O, Singareddy A, Implementation of RECIST 1.1 in Lung Cancer, White Paper, PAREXEL, May 2018
- Bohnsack O, Evolution of Imaging Endpoints in Clinical Trials, presentation at IO360, 2017
- Miller D, Bohnsack O, Jacobs R, The Past, Present & Future of Cancer Immunotherapy: An Overview, White Paper, PAREXEL 2015
- Luby K, Bohnsack O, Ferreira A, Schmid A, Vilardi J, Assessing Prostate Cancer on Imaging in Clinical Trials, A Summary of Recommendations from PAREXEL Medical Imaging, White Paper, PAREXEL 2015

- Storim L., Bohnsack O., Lesch M., Higher Data Reliability of Blinded Independent Central Review compared to Local Evaluation, poster ECR 2015, 10.1594/ecr2015/C-0225
- Bohnsack O., Ludajic K, Hoos A Adaptation and modification of the immune related response criteria irRC: irRECIST, poster ESMO 2014, Ann Oncol (2014) 25 (suppl 4): iv369
- Bohnsack O., Lesch M., Urbank A., Blinded, independent, central image review in oncology trials: How the study endpoint impacts the adjudication rate, poster ESR 2014, 1705
- Bohnsack O, Schmid MS, Chen L, Chandler B, Pitfalls with the independent audit method of PFS endpoint trials with central imaging, ECCO poster 1176, 2013
- Bohnsack O, Schmid MS, Chen L, Chandler B, Challenges in the ODAC proposed Central Image Review Audit methodology, ASCO Abstract 117705, 2013
- Urbank A., Bohnsack O., Blinded, independent, central image review in oncology trials: Will the study endpoint impact the adjudication rate or will the adjudication rate impact the study endpoint?, poster EACR-22 2012, program and abstract book number: 765
- Gebauer B, Bohnsack O, Riess H, Radiological Evaluation of Tumor Response in Oncological Studies (Tumor Response Evaluation), Fortschr Röntgenstr 2011; 183: 695–703
- Bohnsack O, Schmid A, RECIST in the Real World of Cancer Research, Applied Clinical Trials, May 2010 ASCO Special Edition
- Bohnsack O, Core Strength, Int. Clin. Trials Feb. 2010
- Kemsley K, Ghiorghiu D, Bohnsack O, et.al., Use of Progression Free Survival in advanced melanoma: Comparison of central and site review of RECIST data in a randomised phase II trial, Poster ASCO 2009
- Wolchok JD, Hoos A, Bohnsack O, et.al., Guidelines for the Evaluation of Immune Therapy Activity in Solid Tumors: Immune-Related Response Criteria, Clin Cancer Res 2009;15(23) December 1, 2009
- Chica S, Bohnsack O, Schmid A, Recommendations For Consistent Application of RECIST 1.1 To Specific Trial Indications, White Paper, PAREXEL 2009
- Lesch M, Bohnsack O, Unexpected Benefits From Centralized Imaging Reviews, Int. Clin. Trials 2008
- Bohnsack O, Seeing is Believing, Good Clinical Practice Journal, Jan. 2006