

CURRICULUM VITAE

PERSONAL DETAILS

Full Name: Maria De Santis

Title Dr (Doctor), PD (Privatdozentin),

Date of birth: 02.01.1964

Place of birth: Vienna

Citizenship: Austrian

Current residency: Germany

Österreichische Ärztekammer (Austrian licence): 27904-56

UK-GMC licence 2015- 2019: 7502712

Deutsche Approbation: 27.03.2018

Deutsche Ärztekammer (German Licence): 80276001086119033658

Current appointment (started 01 April 2018):

Chair of Section for Interdisciplinary Genitourinary Cancer Medicine at the Charité Medical University Hospital, Berlin, Germany (“Leitung der Sektion für interdisziplinäre Uro-Onkologie im Bereich der Charité - Universitätsmedizin Berlin)

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Mailing address: Department of Urology, Section for Interdisciplinary Genitourinary Oncology, Charitéplatz 1, 10117 Berlin, Germany

And

Adjunct Professorship: Adjunct Professor for Oncology at the Department of Urology, Medical University of Vienna, Austria

Last appointment May 2015 - March 2018

Department: Warwick Medical School

Division: Health Sciences, Cancer Research Unit followed by new Division of Clinical Trials Unit

Unit: Clinical Trials Unit

Title of appointment: Associate Clinical Professor for Oncology

Clinical work: Queen Elizabeth Hospital, at University Hospitals Birmingham, Cancer Centre, Genitourinary Cancer Service, Birmingham, UK

Title: Honorary Consultant for Medical Oncology

Education/Qualifications:

Oct 2008 ***Post-doctoral study***

Habilitation

Paracelsus Medical University (Salzburg, Austria)

Oct 2002 ***Certification in European Medical Oncology*** (recertification 2007, 2012 and 2018) at European Society of Medical Oncology (ESMO)

30.09.1999 ***Certification of higher specialist training***

Diplom Fachärztin für Innere Medizin (Hämato-Onkologie)
(degree certificate issued 20.08.2001)

Austrian Medical Chamber – ÖÄK (Vienna, Austria)
Oncology and Haematology

- 30.09.1997 **Certification of specialist training**
Diplom Facharzt für Innere Medizin
(degree certificate issued 10.11.1998)
Austrian Medical Chamber - ÖÄK (Vienna, Austria)
Internal medicine (general; oncology and haematology; cardiology)
- 01.07.1988 **Doctor in medicine (MD)**
Doctoris universae medicinae nomen et honores
University of Vienna (Vienna, Austria)
- 30.06.1982 **Matura**
(Austrian equivalent of A-levels)

Appointments held:

- Kaiser Franz Josef-Spital, SMZ-Süd** Vienna, Austria
- 2008-2015 Associate Professor (senior lecturer) at 3rd Medical Department, Centre of Oncology and Haematology
- 2004-2015 Chair of the genitourinary cancer service at the 3rd Medical Department, Centre of Oncology and Haematology
- 09/1999-2015 Senior faculty member at 3rd Medical Department, Centre of Oncology and Haematology

- Memorial Sloan Kettering Cancer Centre** New York, USA
- 2003 Observership during sabbatical year, Genitourinary Oncology Service

Training appointments

- 09/1997- **Higher specialist training, Haematology and Oncology**
09/1999 Kaiser Franz Josef-Spital, SMZ-Süd, Vienna
3rd Medical Department, Centre of Oncology and Haematology
- 10/1992- **Specialist training (internship), Internal Medicine**
09/1997 Kaiser Franz Josef-Spital, SMZ-Süd, Vienna
3rd Medical Department, Centre of Oncology and Haematology
- 07/1996- **Specialist training (rotation), Cardiology**
12/1996 Kaiser Franz Josef-Spital, SMZ-Süd, Vienna
5th Medical Department with Cardiology
- 01/1991- **GP training (internship), paediatrics**
09/1991 St. Anna Kinderspital (paediatric hospital), Vienna
- 07/1990- **GP training (internship), accident surgery**
12/1990 UKH Meidling (trauma hospital), Vienna
- 04/1990- **GP training (internship), paediatrics**
06/1990 St. Anna Kinderspital (paediatric hospital), Vienna

01/1990- **Medical Apprenticeship**
03/1990 Dr. Cornelius Sellner (GP), Vienna

02/1988- **Assistant**
12/1989 Dr. Cornelius Sellner (GP), Vienna

Awards:

2016-2019 Adjunct Professorship at Department of Urology, Medical University of Vienna, Austria

Membership of professional societies, scientific boards and study groups:

ASCO, DGU, EAU, EORTC, ESMO, ÖGHO, ÖGU/AUO

Postgraduate Teaching & Professional Development for Oncologists and Urologists

- Austrian Association of Haematology and Oncology (OeGHO) and European School of Oncology (ESO) annual course *Onkologie in Klinik und Praxis*: Lectures on testicular cancer therapy strategies (2004-2015)
- Professional development sessions on prostate cancer treatment in Vienna, Vorchdorf, Stegersbach and Graz, Austria (Apr 2015)
- EAU Section of Urology (ESU) Course *Comorbidity in oncology* at the 30th European Association of Urology (EAU) Annual Meeting: *If not possible (patient unfit for surgery), considering alternative procedures; Are they always feasible in senior adults?* (Mar 2015)
- 2nd European School of Oncology (ESO) Prostate Cancer Observatory: Innovation and care in the next 12 months at the 30th European Association of Urology (EAU) Annual Meeting: *The medical oncologist's perspective* (Mar 2015)
- Professional development sessions on CRPC in Salzburg, Krems and Vienna, Austria (Feb 2015)
- Professional development on mRCC at Kaiser Franz Josef-Hospital in Vienna, Austria (Dec 2014)
- Professional development for Urologists, Vienna, Austria: *New agents in uro-oncology: Role of surgeons?* (Feb 2014)
- Grand Round at Vienna University Hospital, Department of Urology, hosted by Prof. Shariat: Lecture *Prostate Cancer: chemotherapy – still needed?* (Dec 2013)
- First Interdisciplinary Prostate Cancer Update Meeting: *The Future is now* at Medical University of Vienna, Department of Urology, hosted by Prof. Shariat: Lecture *Castration-resistant prostate cancer: study designs, endpoints and how to move forward* (Nov 2013)
- Professional development at Donauspital (Vienna Hospital Group): Update on Genitourinary Cancer Treatment 2013: Lecture *Urothelial Cell Cancer Therapy* (Nov 2013)
- EAU Section of Urology (ESU) Medical Oncology Course on Genitourinary Cancer at the 5th European Multidisciplinary Meeting on Urological Cancers 2013: Lecture and Interactive Case Discussion *Bladder cancer: What is the advised combination therapy and when? Unmet medical needs in bladder cancer* (Nov 2013)
- Professional development at Leoben Hospital: Lecture *Update on bladder cancer treatment* (Oct 2013)
- 289th European School of Oncology (ESO) e-oncoreview: Expert and discussant in e-session *Management of castration resistant prostate cancer: response, progression and endpoints for clinical trials and daily practice* (Aug 2013)
- Professional development on mCRPC for Carinthian Urologists: Lecture *2nd line treatment of metastatic prostate cancer – What? When? For whom?* (May 2013)
- Professional development at University of Innsbruck, Urology Department, on Metastatic Castration-Resistant Prostate Cancer: Lecture *2nd-line treatment of metastatic prostate cancer* (Mar 2013)
- Professional development at Urology Department Vöcklabruck for Austrian Urologists: Lecture *Management of the metastatic urothelial cell carcinoma* (Feb 2013)

- Professional development, Austrian Society of Urology and Andrology (OeGU): Lecture *Management of metastatic urothelial cancer* (Nov 2012)
- Chair of the *Meet the Expert* workshop *How to set up a multidisciplinary clinic* at the 4th International Symposium on Hormonal Treatment of Prostate Cancer (Oct 2012)
- Professional development at Hietzing Hospital, Vienna, Department of Oncology: Lecture *Management of advanced urothelial cancer* (Oct 2012)
- Professional development at Donauspital Vienna, Department of Oncology: Lecture on prostate cancer treatment (Sep 2012)
- Professional development at University Hospital Basel, Switzerland: Lecture on prostate cancer chemotherapy (Aug 2012)
- Professional development for Austrian Urologists and Oncologists: Lecture *Which treatment for which prostate cancer patient?* (Mar 2012)
- Professional development for Austrian Oncologists, Styria, hosted by Fürstenfeld Hospital, Department of Oncology: Lecture on prostate cancer (Mar 2012)
- Professional development at Austrian Association of Urology and Andrology (OeGU) fellows: Lectures on systemic bladder and testicular cancer therapy (2006-2008) and on the management of metastatic urothelial cancer (2012)
- Visiting professor at Institut Gustave Roussy, Villejuif, Paris, France: Lecture *Systemic treatment of bladder cancer* (Feb 2012)
- German Working Group on Oncology (AKO) and Austrian Urologic Oncology Working Group (AUO) Intensive Course on Urologic Oncology for German Urologists: Lecture *Neoadjuvant, adjuvant and palliative chemotherapy of the urothelial cell carcinoma* (Feb 2012)
- German Urology Group on Urologic Oncology (AKO) professional development for German Urologists: Presentation on neoadjuvant chemotherapy for bladder cancer (Jan 2012)
- Professional development at the Austrian Association of Pharmacists: Lectures on genitourinary cancers (Nov 2011)
- Professional development for University Hospital Tübingen, Department of Urology staff (Oct 2011)
- Opponent for PhD student Milada Cvancarova Småstuen (University Hospital Oslo): Evaluation of doctoral degree thesis (Sep 2011)
- Visiting professorship: Lecture at Geneva University Hospital (Bladder Cancer, Treatment Strategies) (Apr 2011)
- 21st Professional development course in clinical oncology for medical doctors, St. Gallen, Switzerland: *Bladder cancer treatment in patients unfit for cisplatin* (Feb 2011)
- Austrian Urologic Oncology Working Group (AUO) intensive course on systemic therapy of genitourinary cancers for medical assistants of the Austrian Society of Urology and Andrology (OeGU): Lecture on systemic therapy of urothelial and testicular cancer and discussant (Nov 2010)
- Professional development for Hanover Medical School: Presentation *State of the Art: Advanced urothelial cancer, medical treatment* (June 2010)
- Professional development for Kaiser Franz Josef-Hospital Vienna staff members: Lecture *Systemic renal cell carcinoma therapy: Treatment with tyrosine kinase inhibitors* (2007) and presentation of most important ASCO findings on metastatic renal cell carcinoma therapy (2008)
- *Oncologic Nursing* professional development for nurses in Vienna, Austria: Lectures on urothelial cancers and *Tumour entities, management characteristics and their treatment: Tumours of the male genital tract* (2005, 2008)
- Austrian Urologic Oncology Working Group (AUO) and Austrian Urology Association (OeGU) intensive course on systemic therapy of urological tumours: Lecture *Systemic therapy of urothelial and testicular cancer* (Nov 2008)
- Professional development at Feldkirch Hospital, Urology Department: Presentation on renal cell cancer (Apr 2008)
- Austrian Working Group on Urologic Oncology (AUO) and Austrian Residents' Working Group professional development on invasive bladder cancer: Lecture on radiotherapy (Nov 1999)

External examinations board

- ESMO Examination Working Group membership 2012-2014. This commitment involves the annual development of ESMO exam questions (ESMO certificate for medical oncology and haematology) for European and international medical oncologists and haematologists.

RESEARCH AND PUBLICATIONS

a) **Peer Reviewed Research Publications (available on PubMed)**

1. Witjes JA, Babjuk M, Bellmunt J, Bruins HM, De Reijke TM, **De Santis M**, et al Eur Urol. EAU-ESMO Consensus Statements on the Management of Advanced and Variant Bladder Cancer-An International Collaborative Multistakeholder Effort†: Under the Auspices of the EAU-ESMO Guidelines Committees. Eur Urol. 2020 Feb;77(2):223-250. doi: 10.1016/j.eururo.2019.09.035. Epub 2019 Nov 19.
2. Horwich A, Babjuk M, Bellmunt J, **De Santis M**, et al EAU-ESMO consensus statements on the management of advanced and variant bladder cancer-an international collaborative multi-stakeholder effort: under the auspices of the EAU and ESMO Guidelines Committees†. Ann Oncol. 2019 Nov 1;30(11):1697-1727. doi: 10.1093/annonc/mdz296.
3. Van den Broeck T, van den Bergh RCN, Briers E, Cornford P, Cumberbatch M, Tilki D, **De Santis M**, Fanti S, Fossati N, Gillessen S, Grummet JP, Henry AM, Lardas M, Liew M, Mason M, Moris L, Schoots IG, van der Kwast T, van der Poel H, Wiegel T, Willemse PM, Rouvière O, Lam TB, Mottet N. Biochemical Recurrence in Prostate Cancer: The European Association of Urology Prostate Cancer Guidelines Panel Recommendations. Eur Urol Focus. 2020 Mar 15;6(2):231-234. doi: 10.1016/j.euf.2019.06.004. Epub 2019 Jun 24.
4. Lam TBL, MacLennan S, Plass K, Willemse PM, Mason MD, Cornford P, Donaldson J, Davis NF, Dell'Oglio P, Fankhauser C, Grivas N, Ingels A, Lardas M, Liew M, Pang KH, Paterson C, Omar MI, Zattoni F, Buddingh KT, Van den Broeck T, Cumberbatch MG, Fossati N, Gross T, Moris L, Schoots IG, van den Bergh RCN, Briers E, Fanti S, **De Santis M**, Gillessen S, Grummet JP, Henry AM, van der Poel HG, van der Kwast TH, Rouvière O, Tilki D, Wiegel T, N'Dow J, Van Poppel H, Mottet N. Study Protocol for the DETECTIVE Study: An International Collaborative Study To Develop Consensus Statements for Deferred Treatment with Curative Intent for Localised Prostate Cancer. Eur Urol. 2019 Apr;75(4):699-702. doi: 10.1016/j.eururo.2018.11.009. Epub 2018 Nov 22. No abstract available. PMID: 30473433 Free Article
5. Retz M, Bedke J, Bögemann M, Grimm MO, Zimmermann U, Müller L, Leiber C, Teber D, Wirth M, Bolenz C, van Alphen R, **De Santis M**, Beeker A, Lehmann J, Indorf M, Frank M, Bokemeyer C, Gschwend JE. SWITCH II: Phase III randomized, sequential, open-label study to evaluate the efficacy and safety of sorafenib-pazopanib versus pazopanib-sorafenib in the treatment of advanced or metastatic renal cell carcinoma (AUO AN 33/11). Eur J Cancer. 2019 Jan;107:37-45. doi: 10.1016/j.ejca.2018.11.001. Epub 2018 Dec 7.
6. Afshar M, Patel HRH, **De Santis M**, Tanner JR, O'Neill T, Evison F, James ND, Selby PJ, Patel P. Do Learning Disabilities Affect Testicular Cancer Survival: A National Cohort

- Study Between 2001 and 2015. Eur Urol Oncol. 2019 Jan 14. pii: S2588-9311(18)30216-5. doi: 10.1016/j.euo.2018.12.008. [Epub ahead of prin. PMID: 31411979]
7. Moschini M, Shariat SF, Rouprêt M, **De Santis M**, Bellmunt J, Sternberg CN, Tombal B, Collette L. *Impact of Primary Tumor Location on Survival from the European Organization for the Research and Treatment of Cancer Advanced Urothelial Cancer Studies.* J Urol. 2018 May;199(5):1149-1157. doi: 10.1016/j.juro.2017.11.068. Epub 2017 Nov 20
 8. Moldovan PC, Van den Broeck T, Sylvester R, Marconi L, Bellmunt J, van den Bergh RCN, Bolla M, Briers E, Cumberbatch MG, Fossati N, Gross T, Henry AM, Joniau S, van der Kwast TH, Matveev VB, van der Poel HG, **De Santis M**, Schoots IG, Wiegel T, Yuan CY, Cornford P, Mottet N, Lam TB, Rouvière O. *What Is the Negative Predictive Value of Multiparametric Magnetic Resonance Imaging in Excluding Prostate Cancer at Biopsy? A Systematic Review and Meta-analysis from the European Association of Urology Prostate Cancer Guidelines Panel.* Eur Urol. 2017 Aug;72(2):250-266. doi: 10.1016/j.eururo.2017.02.026. Epub 2017 Mar 21.
 9. Fossati N, Willemse PM, Van den Broeck T, van den Bergh RCN, Yuan CY, Briers E, Bellmunt J, Bolla M, Cornford P, **De Santis M**, MacPepple E, Henry AM, Mason MD, Matveev VB, van der Poel HG, van der Kwast TH, Rouvière O, Schoots IG, Wiegel T, Lam TB, Mottet N, Joniau S. *The Benefits and Harms of Different Extents of Lymph Node Dissection During Radical Prostatectomy for Prostate Cancer: A Systematic Review.* Eur Urol. 2017 Jul;72(1):84-109. doi: 10.1016/j.eururo.2016.12.003. Epub 2017 Jan 24.
 10. Lardas M, Liew M, van den Bergh RC, **De Santis M**, Bellmunt J, Van den Broeck T, Cornford P, Cumberbatch MG, Fossati N, Gross T, Henry AM, Bolla M, Briers E, Joniau S, Lam TB, Mason MD, Mottet N, van der Poel HG, Rouvière O, Schoots IG, Wiegel T, Willemse PM, Yuan CY, Bourke L. *Quality of Life Outcomes after Primary Treatment for Clinically Localised Prostate Cancer: A Systematic Review.* Eur Urol. 2017 Jul 27. pii: S0302-2838(17)30535-3. doi: 10.1016/j.eururo.2017.06.035. [Epub ahead of print] Review.
 11. Stewart GD, **De Santis M**, Escudier B, Powles T, Sonpavde G. *Immunotherapy for Renal Cancer: Sequencing and Combinations.* Eur Urol Focus. 2016 Dec 15;2(6):582-588. doi: 10.1016/j.euf.2017.04.002. Epub 2017 Apr 20. Review.
 12. Briganti A, **De Santis M**, Giannarini G, Sweeney CJ. *Delivering Optimal Care for Metastatic Prostate Cancer: A Strengthening Alliance Between Urologists and Medical Oncologists.* Eur Urol Focus. 2016 Dec;2(5):463-464. doi: 10.1016/j.euf.2016.11.017. Epub 2016 Dec 13.
 13. Caffo O, Thompson C, **De Santis M**, Kragelj B, Hamstra DA, Azria D, Fellin G, Pappagallo GL, Galligioni E, Choudhury A. *Concurrent gemcitabine and radiotherapy for the treatment of muscle-invasive bladder cancer: A pooled individual data analysis of eight phase I-II trials.* Radiother Oncol. 2016 Oct 5
 14. Dittrich C, Kosty M, Jezdic S, Pyle D, Berardi R, Bergh J, El-Saghir N, Lotz JP, Österlund P, Pavlidis N, Purkalne G, Awada A, Banerjee S, Bhatia S, Bogaerts J, Buckner J, Cardoso F, Casali P, Chu E, Close JL, Coiffier B, Connolly R, Coupland S, De Petris L, **De Santis M**, de Vries EG, Dizon DS, Duff J, Duska LR, Eniu A, Ernstoff M, Felip E, Fey MF, Gilbert J, Girard N, Glaudemans AW, Gopalan PK, Grothey A, Hahn SM, Hanna D, Herold C, Herrstedt J, Homicsko K, Jones DV Jr, Jost L, Keilholz U, Khan S, Kiss A, Köhne CH,

Kunstfeld R, Lenz HJ, Lichtman S, Licitra L, Lion T, Litière S, Liu L, Loehrer PJ, Markham MJ, Markman B, Mayerhofer M, Meran JG, Michielin O, Moser EC, Mountzios G, Moynihan T, Nielsen T, Ohe Y, Öberg K, Palumbo A, Peccatori FA, Pfeilstöcker M, Raut C, Remick SC, Robson M, Rutkowski P, Salgado R, Schapira L, Schernhammer E, Schlumberger M, Schmoll HJ, Schnipper L, Sessa C, Shapiro CL, Steele J, Sternberg CN, Stiefel F, Strasser F, Stupp R, Sullivan R, Tabernero J, Travado L, Verheij M, Voest E, Vokes E, Von Roenn J, Weber JS, Wildiers H, Yarden Y.

ESMO/ASCO Recommendations for a Global Curriculum in Medical Oncology Edition 2016.

ESMO open. 2016 Sep 29;1(5):e000098. eCollection 2016.

15. De Santis M, Wiechno PJ, Bellmunt J, Lucas C, Su WC, Albiges L, Lin CC, Senkus-Konefka E, Flechon A, Mourey L, Necchi A, Loidl WC, Retz MM, Vaissière N, Culine S. *Vinflunine-gemcitabine versus vinflunine-carboplatin as first-line chemotherapy in cisplatin-unfit patients with advanced urothelial carcinoma: results of an international randomized phase II trial (JASINT1).* Ann Oncol. 2016 Mar;27(3):449-54.
16. Eichelberg C, Vervenne WL, De Santis M, Fischer von Weikersthal L, Goebell PJ, Lerchenmüller C, Zimmermann U, Bos MM, Freier W, Schirrmacher-Memmel S, Staehler M, Pahernik S, Los M, Schenck M, Flörcken A, van Arkel C, Hauswald K, Indorf M, Gottstein D, Michel MS. *SWITCH: A randomised, sequential, open-label study to evaluate the efficacy and safety of Sorafenib-sunitinib versus Sunitinib-sorafenib in the treatment of metastatic renal cell cancer.* Eur Urol. 2015 May 4. pii: S0302-2838(15)00319-X. doi: 10.1016/j.eururo.2015.04.017.
17. Gillessen S, Omlin A, Attard G, de Bono JS, Efsthathiou E, Fizazi K, Halabi S, Nelson PS, Sartor O, Smith MR, Soule HR, Akaza H, Beer TM, Beltran H, Chinnaiyan AM, Daugaard G, Davis ID, De Santis M, Drake CG, Eeles RA, Fanti S, Gleave ME, Heidenreich A, Hussain M, James ND, Lecouvet FE, Logothetis CJ, Mastris K, Nilsson S, Oh WK, Olmos D, Padhani AR, Parker C, Rubin MA, Schalken JA, Scher HI, Sella A, Shore ND, Small EJ, Sternberg CN, Suzuki H, Sweeney CJ, Tannock IF, Tombal B. *Management of patients with advanced prostate cancer: recommendations of the St Gallen Advanced Prostate Cancer Consensus Conference (APCCC) 2015.* Ann Oncol. 2015 Aug;26(8):1589-604. doi: 10.1093/annonc/mdv257. Epub 2015 Jun 3.
18. Sternberg CN, Skoneczna I, Kerst JM, Albers P, Fossa SD, Agerbaek M, Dumez H, De Santis M, Théodore C, Leahy MG, Chester JD, Verbaeys A, Daugaard G, Wood L, Witjes JA, de Wit R, Geoffrois L, Sengelov L, Thalmann G, Charpentier D, Rolland F, Mignot L, Sundar S, Symonds P, Graham J, Joly F, Marreaud S, Collette L, Sylvester R, for the European Organisation for Research and Treatment of Cancer Genito-Urinary Cancers Group; Groupe d'Etude des Tumeurs Urogénitales; National Cancer Research Institute Bladder Cancer Study Group; National Cancer Institute of Canada Clinical Trials Group; German Association of Urologic Oncology (AUO). *Immediate versus deferred chemotherapy after radical cystectomy in patients with pT3-pT4 or N+ MO urothelial carcinoma of the bladder (EORTC 30994): An intergroup, open-label, randomised phase 3 trials.* Lancet Oncol. 2015 Jan;(16):76-86. doi: 10.1016/S1470-2045(14)71160-X. [Epub 2014 Dec 11].
19. De Santis M, Bachner M, Cerveny M, Kameträser G, Steininger T, Königsberg R, Schratter-Sehn A, Sedlmayr F, Dittrich C. *Combined chemo-radiotherapy with Gemcitabine in patients with locally advanced inoperable transitional cell carcinoma (TCC) of the urinary bladder and/or in patients ineligible for surgery: A phase I trial.* Ann Oncol. 2014 Sep;25(9):1789-94. doi: 10.1093/annonc/mdu209

20. Bellmunt J, von der Maase H, Mead G, Skoneczna I, **De Santis M**, Daugaard G, Boehle A, Chevreau C, Paz-Ares L, Laufman L, Winquist E, Raghavan D, Marreaud S, Collette S, Sylvester R, de Wit R.
A Randomised Phase III Study comparing Paclitaxel/Cisplatin/Gemcitabine in Patients with Locally Advanced or Metastatic Urothelial Cancer without prior Systemic Therapy. An Intergroup Study of EORTC (EORTC 30987).
J Clin Oncol. 2012 Apr 1; 30(10):1107-13. Epub 2012 Feb 27.
21. de Wit R, Skoneczna IA, Daugaard G, **De Santis M**, Garin A, Aass N, Witjes JA, Albers P, White J, Germà i Lluch JR, Marreaud SI, Collette L.
A Randomised Phase III Study comparing Paclitaxel (Taxol) and BEP (T-BEP) to Standard BEP in Intermediate-Prognosis Germ-Cell Cancer (GCC). An Intergroup Study of EORTC, German TCSG/AUO, MRC/UK NCRI and Spanish GCC Group (EORTC 30983).
J Clin Oncol. 2012 Jan 10; 30(2):191-9. Epub 2011 Dec 12.
22. **De Santis M**, Bellmunt J, Mead G, Kerst JM, Leahy M, Maroto P, Gil T, Marreaud S, Daugaard G, Skoneczna I, Collette S, Lorent J, de Wit R, Sylvester R.
A Randomised Phase II/III Trial Assessing Gemcitabine/Carboplatin and Methotrexate/Carboplatin/Vinblastine in Patients with Advanced Urothelial Cancer who are unfit for Cisplatin-Based Chemotherapy: Phase III-Results of EORTC Study 30986.
J Clin Oncol. 2012 Jan 10; 30(2):191-9. Epub 2011 Dec 12
23. Bachner M, Loriot Y, Gross-Goupil M, Zucali PA, Horwich A, Germa-Lluch JR, Kollmannsberger C, Stoiber F, Fléchon A, Oechsle K, Gillessen S, Oldenburg J, Cohn-Cedermark G, Daugaard G, Morelli F, Sella A, Harland S, Kerst M, Gampe J, Dittrich C, Fizazi K, **De Santis M**.
2-¹⁸Fluoro-Deoxy-D-Glucose Positron Emission Tomography (FDG-PET) for Postchemotherapy Seminoma Residual Lesions: A Retrospective Validation of the SEMPET Trial.
Ann Oncol. 2012 Jan;23(1):59-64.
24. Königsberg R, Obermayr E, Bises G, Pfeiler G, Gneist M, Wrba F, **De Santis M**, Zeillinger R, Hudec M, Dittrich C.
Detection of EpCAM Positive and Negative Circulating Tumour Cells in Metastatic Breast Cancer Patients.
Acta Oncol. 2011 Jun;50(5):700-10.. [Epub ahead of print]
25. Daugaard G, Skoneczna I, Aass N, de Wit R, **De Santis M**, Dumez H, Marreaud S, Collette L, Lluch JR, Bokemeyer C, Schmoll HJ.
A Randomised Phase III Study comparing Standard Dose BEP with Sequential High-Dose Cisplatin, Etoposide, and Ifosfamide (VIP) plus Stem-Cell support in Males with Poor-Prognosis Germ-Cell Cancer. An Intergroup Study of EORTC, GTCSG, and Grupo Germinal (EORTC 30974).
Ann Oncol. 2011 May;22(5):1054-61.
26. **De Santis M**, Bellmunt J, Mead G, Kerst JM, Leahy M, Maroto P, Skoneczna I, Marreaud S, de Wit R, Sylvester R.
Randomised Phase II/III Trial assessing Gemcitabine/Carboplatin (GC) and Methotrexate/Carboplatin/Vinblastine (M-CAVI) in Patients with Advanced Urothelial Cancer who are unfit for Cisplatin Based Chemotherapy: Phase II Results of EORTC study 30986.
J Clin Oncol 27(33):5634-5639, 2009
27. Fizazi K, Oldenburg J, Dunant A, Chen I, Salvioni R, Hartmann JT, **De Santis M**, Daugaard G, Flechon A, De Giorgi U, Tjulandin S, Schmoll HJ, Bouzy J, Fossa SD, Fromont G.

Assessing Prognosis and Optimizing Treatment in Patients with Postchemotherapy viable Nonseminomatous Germcell Tumours (NSGCT): Results of the sCR2 International Study.
Ann Oncol 19:259-364, 2008

28. Königsberg R, Rögelsperger O, Jäger W, Thalhammer T, Klimpfinger M, **De Santis M**, Hudec M, Dittrich C.
Cell Cycle Dysregulation Influences Survival in High Risk Breast Cancer Patients.
Cancer Invest 26(7):734-40, 2008
29. Sellner F, Sobhian B, **De Santis M**, Pont J, Staettner S, Sellner S, Karner J, Klimpfinger M.
Well or Poorly Differentiated Non-Functioning Neuroendocrine Carcinoma of the Pancreas: A single Institution Experience with 17 cases.
Eur J Surg Oncol 34:191-195, 2008
30. Sellner F, Tykalsky N, **De Santis M**, Pont J, Klimpfinger M.
Solitary and Multiple Isolated Metastases of Clear Cell Renal Carcinoma to the Pancreas: An Indication for Pancreatic Surgery.
Ann Surg Oncol 13:75-85, 2006
31. Culine S, Theodore C, **De Santis M**, Bui B, Demkow T, Lorenz J, Rolland F, Delgado FM, Longerey B, James N.
A Phase II Study of Vinflunine in Bladder Cancer Patients progressing after First-Line Platinum-Containing Regimen.
Br J Cancer 94:1395-1401, 2006
32. Becherer A, **De Santis M**, Karanikas G, Szabó M, Bokemeyer C, Dohmen BM, Pont J, Dudczak R, Dittrich C, Kletter K.
FDG PET is superior to CT in the Prediction of Viable Tumour in Post-Chemotherapy Seminoma Residuals.
Eur J Radiol 54:284-288, 2005
33. Albrecht W, **De Santis M**.
Innovative Mouse Model for Postchemotherapy Fertility Evaluation.
J Androl. 2005 Mar-Apr;26(2):169
34. **De Santis M**, Becherer A, Bokemeyer C, Stoiber F, Oechsle K, Sellner F, Lang A, Kletter K, Dohmen BM, Dittrich C, Pont J.
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d) Book Chapters

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Chapter *Advanced seminoma*:
Wiley Blackwell: Textbook on *Testicular Cancer* edited by Alan Horwich, Robert Huddart and Larry Einhorn.
2. **De Santis M**, Steininger T.
Chapter *Monozentrische Studie*:
Springer: *Handbuch Ethik und Recht der Forschung am Menschen* [in German] edited by Christian Lenk, Gunnar Duttge and Heiner Fangerau. (2014)
3. Steininger T, **De Santis M**.
Chapter *Lebensqualität – Quality of Life (QoL)*:
Springer: *Handbuch Ethik und Recht der Forschung am Menschen* [in German] edited by Christian Lenk, Gunnar Duttge and Heiner Fangerau. (2014)
4. **De Santis M**, Galsky M.
Chapter *Treatment of Poor Risk Patients*:
Wiley: *Bladder Cancer Text Book Diagnosis and Clinical Management* edited by Seth Lerner, Cora Stenberg and Mark Schoenberg. (2014)
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Chapter *Metastatic Bladder Cancer*:
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Chapter *Metastatic Bladder Cancer*:
Thieme: *Bladder Cancer – muscle-invasive, locally advanced, metastatic; Guidelines for clinical practice* by Arnulf Stenzl, Maria De Santis, Georgios Gakis, Jürgen Gschwend, MA Kuczyk. (2012)

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8. **De Santis M**, Bachner M.
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Chapter *Positron Emission Tomography (PET) in Germ Cell Tumours (GCT)*:
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11. **De Santis M**.
Chapter *Penile Cancer*.
Springer: *Uro-Oncology* edited by Rübben H. (2009)

Research Grants and Pharma Contracts:

Available on request

ADMINISTRATION AND OTHER SERVICE

Administration and Contributions to the University of Warwick and its development 2015-2018:

- Advisory role and reviewer for Warwick Evidence Review Group (ERG) on a single technology appraisal project as part of the National Institute of Health and Care Excellence (NICE) process. The project was titled “Pembrolizumab for previously treated advanced or metastatic urothelial cancer” [ID1019]
- Involvement in Warwick University trials
- Advisory role for Chemistry Department (Prof Peter Sadler) on development of precious metals (Osmium, Iridium) for the treatment of different cancers
- Member of the review panel of PhD student Ms Hattie Mintz 2016
- Member of the PhD exam panel of Ms Viva - Sanchia Goonewardene on 03.02.2017
- PhD Supervision:
Since October 2016: Supervision of PhD of Dr Omar R. Abdullah together with Prof Annie Young. The student comes from the conflict region North Iraq, his family and his mentoring professor have been exposed to death threats. He is being funded by a CARA Fellowship. The thesis is a two-part project with the working title: Venous thromboembolism in muscle invasive, locally advanced or metastatic urothelial cancer during and after chemotherapy.
- Representing the University of Warwick at external meetings organized by international scientific organizations or universities (see CV below): EAU, ESMO, ASCO, ASCO-GUCA, DGHO, S3 Leitlinien Germany, University of Sao Paolo (Einstein Hospital), University of Vienna (Medical School – MUW, Urology)

NHS, clinical trials services

- Scientific Advisory Committee (SAC) review board member until March 2018

NATIONAL AND INTERNATIONAL RECOGNITION

Awards

Mallinckrodt-ÖGN Förderungspreis Nuklearmedizin 2004 der Österreichischen Gesellschaft für Nuklearmedizin, Graz (first prize)

Scientific Programme Committee Member

- Chair of GU prostate cancer track, ESMO 2020
- American Society of Clinical Oncology (ASCO) GU track 2011-2013
- European Society of Medical Oncology (ESMO) GU track 2012, 2014, 2017, 2018, 2019
- ESMO congress educational program track member 2018
- Chair of GU non-prostate track, ESMO 2012
- European Association of Urology Annual Meeting (EAU) since 2013, ongoing
- PROSCA (global prostate cancer conference) organising faculty member 2013- 2017
- BLADDR (Global Bladder Cancer Conference) organising faculty member since 2016 (ongoing)
- Scientific Faculty member of the Annual Meeting of the German, Austrian and Swiss Associations of Haematology and Oncology (DGHO, OeGHO, SGHO) 2011, 2013, 2014

Abstract Discussant (Oral Presentation and Poster Discussions)

- American Society of Clinical Oncology (ASCO) 2006, 2011, 2013, 2015
- American Society of Clinical Oncology (ASCO-GU) 2017
- European Society of Medical Oncology (ESMO) 2012, 2014, 2017

Invited Lectures/Conferences/Plenary and Sub-Plenary Sessions

- ASCO GU Meeting 2017
- Advanced Prostate Cancer Consensus Conference (APCCC) 2015, 2017
- German Cancer Congress (DKK) 2012, 2014
- American Society of Clinical Oncology (ASCO) 2012
- EAU Section of Oncological Urology (ESOU) 2012, 2017
- European Multidisciplinary Meeting on Urological Cancers (EMUC) 2011, 2012, 2014, 2015, 2019
- European Association of Urology Annual Meeting (EAU) 2011-2020
- European Society of Medical Oncology (ESMO) 2010, 2012
- European Cancer Organization (ECCO) 2011, 2013, 2015
- European Consensus Conference on Diagnosis and Treatment of Germ Cell Cancer (EGCCCG) 2006 and 2011

Invited Lectures/Conferences with Unrestricted Grants

- International Symposium on Hormonal Treatment of Prostate Cancer (STOP) 2012, 2014
- European Consensus Panel on metastatic castration-resistant prostate cancer member 2013 (priME Oncology)
- International Oncology Meeting (IOM) 2012

Membership of other scientific Boards, Guidelines and Study Groups

- S3 Guidelines for Bladder Cancer Working Group (Germany), member and chair of systemic treatment group 2012-2015, Update 2018/2019
- EAU-ICUD Muscle-Invasive Bladder Cancer Systemic Treatment co-chair 2014
- EAU-ICUD Prostate Cancer Systemic Treatment co-chair 2014
- EAU Scientific Committee Office member since 2012 - ongoing
- ISSECAM Board of Directors member since 2012 - ongoing
- ESMO Examination Working Group member 2012-2014
- ICUD Testis Cancer Subcommittee on Diagnosis, Staging and Risk Factors member 2009, 2014
- ICUD UTUC (upper tract urothelial cancer) Treatment of Metastatic Cancer Committee member 2012, 2013
- EAU Working Group on Muscle-Invasive and Metastatic Bladder Cancer 2008-2015
- EAU Working Group on Prostate Cancer (Guidelines Group Panel) 2015 - ongoing
- German Testicular Cancer Study Group (GTCSG) member 2007-2015
- EORTC newly founded Genito-Urinary Cancers Group (GUCG) member since 2010 - ongoing
- EORTC Genito-Urinary Track member 2001-2010

Invited speaker/session chair at major conferences & other professional bodies

AMERICAN SOCIETY OF CLINICAL ONCOLOGY (ASCO) ANNUAL MEETING activities

- | | |
|------|---|
| 2016 | Poster presentation, number 4520: Circulating tumor cells (CTC) and HER2 status on CTC and primary tumor in urothelial cancer (UC) patients (pts) refractory to platinum based chemotherapy |
| 2015 | Discussant in GU (Non prostate) Cancer oral abstract session |
| 2012 | Chair of GU Poster Discussion Session |
| 2012 | Presentation of the Highlights of the Day – Genitourinary Cancers |
| 2011 | Discussant in oral presentation session (bladder cancer abstracts) |
| 2006 | Discussant in oral presentation session (testis cancer abstracts) |

AMERICAN SOCIETY OF CLINICAL ONCOLOGY – GENITOURINARY CANCERS MEETING (ASCO GU) – Poster/abstract presentation

- | | |
|------|---|
| 2017 | Invited speaker Educational Session (neoadjuvant therapy of bladder cancer) |
| 2009 | <i>Late toxicity of two cycles PEB (cisplatin, etoposide, bleomycin) in the management of clinical stage I non seminomatous germ cell tumours (NSGCT) of the testis: twenty year experience of the Vienna Testicular Tumour Study Group (VTTSG)</i> |
| 2008 | <i>Randomised phase II/III study assessing gemcitabine/carboplatin (GC) and methotrexate/carboplatin/vinblastine (M-CAVI) in previously untreated patients (pts) with advanced urothelial cancer ineligible for cisplatin based chemotherapy: phase II results of EORTC study 30986</i> |

INTERNATIONAL SYMPOSIUM ON HORMONAL TREATMENT OF PROSTATE CANCER (STOP)

- | | |
|------|---|
| 2014 | Chair of the session <i>Castrate resistant prostate cancer and presentation Systemic/medical treatment: Future of CRPC management</i> |
| 2014 | Chair of the <i>Meet the Expert workshop Talking with your patient: informed consent, communicating bad news</i> |

- 2012 CRPC: *New treatment approaches – developments in targeting the androgen receptor and in chemotherapy*
2012 Chair of the *Meet the Expert* workshop *How to set up a multidisciplinary clinic*

GLOBAL CONGRESS ON PROSTATE CANCER (PROSCA)

- 2017 Organising Committee member, chair and lecture
2016 Organising Committee member, lecture
2015 Organising Committee member, chair
2013 Organising Committee member and session chair

GLOBAL CONGRESS ON BLADDER CANCER (BLADDR)

- 2019 Faculty member, chair
2018 Faculty member, chair
2017 Faculty member, chair
2016 Faculty member

INTERNATIONAL ONCOLOGY MEETING (IOM)

- 2012 *Prostate cancer trial designs and endpoints*

EUROPEAN SOCIETY OF MEDICAL ONCOLOGY (ESMO) Annual Conference activities

- 2020 Chair of GU—Prostate Cancer track
2019 Scientific Board Member
2018 Educational Board Member, invited speaker
2017 Scientific Board Member
2017 Discussant at GU Non-Prostate Tumors Poster Discussion Session
2017 Commentator at ESMO LBA Press Conference
2016 Poster presentation *Global treatment patterns for late-stage prostate cancer: Updated results from ASPIRE-PCa*
2014 *How to deal with unresectable and inoperable bladder cancer* at the Educational Session *Update in GU Oncology*
2014 Chair of Genitourinary Nonprostate Poster Display Session
2014 Co-Chair and Discussant in Genitourinary Prostate Poster Discussion Session
2014 Discussant in Genitourinary Nonprostate Immunotherapy Preferred Paper Session
2012 Chair of Genitourinary Nonprostate session
2010 Chair of the Preferred Paper Session Genitourinary tumours
2010 *Congress Highlights* in plenary session on Genitourinary Tumours

EUROPEAN MULTIDISCIPLINARY MEETING IN UROLOGY CANCER (EMUC)

- 2019 Invited speaker
2018 Invited speaker
2017 Faculty member, session chair, presenter and discussant
2017 Invited case discussion
2016 Faculty member
2016 Chair of Best of Journal session
2016 *Clinical implications of bladder cancer variants: The medical oncologist view*
2016 Presentation at Sanofi satellite symposium
2015 Session chair of oral presentation of best abstract
2015 *Targeted therapies* at Update on Systemic Treatments in Bladder Cancer
2015 Presentation at Astellas mCRPC Satellite Symposium
2012 Chair of the session *Locally advanced bladder cancer*

- 2012 *Optimizing outcomes in metastatic CRPC: a consideration of new and emerging agents at Bayer Satellite Symposium Extending survival for patients with RCC and CRPC: new hope in advanced disease*
2011 *New systemic treatment options in bladder cancer*
2009 Faculty member
2009 *New systemic treatment modalities in advanced bladder cancer*

EUROPEAN ASSOCIATION OF UROLOGY (EAU) Annual Meeting

- 2020 Faculty member, invited speaker, chair function
2019 Faculty member, invited speaker, chair function
2018 Faculty member, chair, presenter
2017 Faculty member, chair, presenter
2016 Faculty member, chair, presenter
2015 Faculty member
2015 Chair of thematic session 09 *Immunotherapy in urologic oncology*
2015 Discussant in plenary session 4 *Controversies in stone management*
2015 ESU Course 05 *Comorbidity in Oncology*
2015 *The medical oncologist's perspective at 2nd ESO Prostate Cancer Observatory: Innovation and care in the next 12 months*
2014 Faculty member
2014 Chair of castration-resistant prostate cancer session
2013 Chair of prostate cancer poster session on systemic treatment
2013 *Bladder cancer: New systemic treatment options – State of the Art*
2012 *Current perspectives of chemotherapy in mCRPC*

EAU SECTION OF ONCOLOGICAL UROLOGY (ESOU)

- 2019 Steering committee member, Faculty
2017 Lecture on Hormone Sensitive Prostate Cancer
2013 Lecture on bladder cancer, systemic treatment and case discussions
2012 Lecture on neoadjuvant bladder cancer chemotherapy

EUROPEAN CANCER ORGANIZATION (ECCO)

- 2015 *Carboplatin based chemotherapy in the GU malignancies (non-prostate) educational session Combined mortality treatment in elderly with bladder cancer*
2015 *Metastatic CRPC: Multiple choices - a double-edged sword?* at Bayer Satellite Symposium
2013 *Preliminary data on feasibility of vinflunine (VFN)-based combinations as 1st line in CDDP-unfit patients (pts) with urothelial carcinoma (UC): VFN/Gemcitabine vs. VFL/CBDCA in a randomised international phase II trial (JASINT 1)*
2013 Chair of Special session *Management of Bladder Cancer*
2011 Chair of the special session *Current issues in the management of germ cell tumours*
2011 *Penile Cancer Chemotherapy* in the special session *The management of Penile Cancer*
2011 Discussant in the proffered papers session *Genitourinary Malignancies – Prostate Cancer*

ANNUAL MEETING OF THE GERMAN, AUSTRIAN AND SWISS ASSOCIATIONS OF HAEMATOLOGY AND ONCOLOGY (DGHO, OeGHO, SGHO)

- 2015 *Inoperable bladder cancer and the role of chemo- and radiotherapy* in the session *Urothelial carcinoma management 2015*
2013 Chair of the session *Bladder, Urothelial and Renal Cancer*

- 2013 *2nd line therapy and new medical options for the treatment of bladder cancer in the near future?*
2013 Chair of Genitourinary Cancers poster session
2011 Chair of Bladder Cancer session
2011 *Bladder cancer: Systemic treatment of advanced disease*
2011 *Indications for chemotherapy for urothelial cancer*, case presentations and interactive group teaching
2010 *Systemic medical treatment of bladder cancer: Which treatment for which patient?*
2006 Chair of Genitourinary Cancers poster sessions
2005 *Advanced bladder cancer chemotherapy*

GERMAN CANCER CONGRESS (DKK)

- 2020 Invited speaker
2018 Invited speaker: *Chemotherapy for hormone sensitive prostate cancer*
2014 *The role of chemotherapy: Indications, Options* at Janssen Satellite Symposium on Prostate Cancer
2012 Chair of continuing education session *Junior academy, practical oncology* and presentation *Tips and Tricks*
2012 *Prognostic and Predictive Factors for Chemotherapy* in the session *Urological Tumours: State of the Art Bladder Cancer*

EUROPEAN CONSENSUS CONFERENCE ON DIAGNOSIS AND TREATMENT OF GERM CELL CANCER

- 2011 *Radiation risk in testis cancer – what is the data?*

ESMO CONFERENCE LUGANO (ECLU)

- 2008 *Highlights in genitourinary tumours (renal, bladder, and testicular cancer)*

Invited speaker or session chair, other

- Nov 2017 Invited speaker at educational event on uro-oncology (Linz, Austria)
May 2017 3rd Austrian-Polish Friends of Urology Association Meeting, (Vienna, Austria)
Dec 2016 Lecture *What is hot in Bladder cancer*, Marberger Memorial Symposium, MUW Vienna
Jun 2006- Annual presentation of the ASCO highlights GU cancer/prostate and bladder at a Post-2016 ASCO Meeting (Vienna and Salzburg, Austria)
Nov 2016 Presentation at *Challenges in the application of guidelines in GU cancer congress* (Athens, Greece)
Apr 2016 Invited speaker at *Urological Cancer Symposium of the RSM Urology Section* (London, United Kingdom)
Apr 2016 Invited speaker at *6th Pierre Fabre Symposium on Bladder Cancer Treatment* (Öhningen, Germany)
Apr 2016 Invited speaker at educational event on uro-oncology (Linz, Austria)
Apr 2016 Invited speaker at *UroRadioOncology Meeting* (Warsaw, Poland)
Feb 2016 Invited speaker at *RSM Section of Urology: Innovation in Urology* (London, K)
Feb 2016 Invitation of *Sociedade Beneficente Israelita Brasileira Albert Einstein* to 3rd *Uro-Oncology International Symposium* (Sao Paolo, Brazil)
Nov 2015 Presentation at the SOGUG Symposium (Madrid, Spain)
Nov 2015 *State of the art of systemic treatment of urothelial carcinoma* for *Barmherzige Brüder* Austria (Vienna)
Oct 2015 *Advanced Prostate Cancer: Towards a new era of treatment?* at German Urology Association (DGU) Congress (Hamburg, Germany)
Nov 2014 Presentation on phase II studies at DESO Seminar (Vienna, Austria)

- Nov 2014 Presentation on CRPC at the Austrian Urologic Oncology Working Group (AUO) Curriculum on medical treatment of GU cancers (Vienna, Austria)
- Sep 2014 Presentation on CTC for *Barmherzige Brüder* Austria (Vienna, Austria)
- Jun 2014 *Current data on neoadjuvant and adjuvant chemotherapy in TCC* at the 4th Urology workshop of Ludwig-Maximilian-University Munich (Tegernsee, Germany)
- May 2014 *Testicular and Prostate Cancer Research – Challenges and Opportunities* at Barts Cancer Institute (London, UK)
- May 2014 Presentation on metastatic bladder cancer at the 11th Carinthian and Styrian Oncology Symposium (Bad Kleinkirchheim)
- Apr 2014 *New mCRPC treatment options* for visitors and patients at Vienna Cancer Day 2014 (Vienna, Austria)
- Apr 2014 *New agents for mCRPC treatment* at Collegium Publicum *Update Urology* (Vienna, Austria)
- Mar 2014 Presentation at the Radium 223 for hormone refractory mCRPC Expert Panel Meeting (Vienna)
- Mar 2014 *Non-surgical bladder cancer treatment* at State of the Art and Horizons in Oncology Meeting (Vienna, Austria)
- Mar 2014 Panel member at the Advanced Prostate Cancer Consensus Conference (St. Gallen, Switzerland)
Oncoforum Urology Suisse 2014 (Zurich, Switzerland)
- Jan 2014 *Advanced and castration resistant prostate cancer: News from 2013* at
- Jan 2014 *Testicular cancer – State of the Art treatment and management in 2014* at Hospital Krems (Krems, Austria)
- Nov 2013 *Chemotherapy of advanced urothelial cell carcinoma of the bladder – how I do it* at the Austrian Fall Meeting of the Working Groups on Andrology and Oncology (Ehrenhausen, Austria)
- Oct 2013 Presentation on urothelial cancer at the Austrian Urologic Oncology Working Group (AUO) Curriculum on medical treatment of GU cancers – Part 2: Renal Cell Cancer (Vienna, Austria)
- Oct 2013 Lecture on CRPC treatment 2014 at Austrian Urologic Oncology Working Group (AUO) Meeting (Vienna, Austria)
- Oct 2013 *Medical treatment of prostate cancer and renal cell cancer – What, when?* at the 82nd Urology Meeting Dresden at the University Hospital of Dresden, Urology Department, hosted by Prof. Wirth (Dresden, Germany)
- May 2013 *Prostate cancer – What to do after diagnosis?* for visitors and patients and *Genitourinary cancers update* for medical doctors at Vienna Cancer Day 2013 (Vienna, Austria)
- Apr 2013 *Bladder Cancer: Gap between standard and daily practice* at the Austrian Society of Oncology and Haematology (OeGHO) Spring Meeting 2013 (Linz, Austria)
- Jan 2013 Faculty member and moderation of the *Applied Translations* session at the Symposium of Translations in Urologic Oncology (Heidelberg, Germany)
- Dec 2012 *Management of locally advanced and metastatic urothelial cancer* at *Oncolunch on urothelial cancers: The urologic-oncological approach with urothelial cancers* (Klagenfurt, Austria)
- Nov 2012 *Are oral chemotherapeutic agents for prostate and renal cell cancer on the rise?* Meeting of the Urology Department of the Hospital Göttlicher Heiland Vienna (Vienna, Austria)
- Sep 2012 *New treatment opportunities and Management of complications* at the Austrian Urologic Oncology Working Group (AUO) Curriculum on medical treatment of GU cancers – Part 1: Prostate Cancer (Vienna, Austria)
- Apr 2012 *New perspectives in oncology* at the Austrian Association of Haematology and Oncology (OeGHO) Spring Meeting and Working Group on Haemato-Oncological Nursing (AHOP) Meeting (Graz, Austria)

- Mar 2012 Presentation on neoadjuvant treatment of bladder cancer at the Austrian Urologic Oncology Working Group (AUO) Meeting (Krems, Austria)
- May 2012 Lecture on mRCC and case presentations at the Swiss workshop *Management of metastatic renal cell carcinoma* (Olten, Switzerland)
- Mar 2012 Invited expert at the Prostate Cancer Certification Committee Meeting Germany (Düsseldorf, Germany)
- Oct 2011 Presentation on P11-1 study (immunotherapy for prostate cancer) at the Austrian Urologic Oncology Working Group (AUO) Meeting (Sebersdorf)
- Oct 2011 *Neoadjuvant bladder cancer chemotherapy: Who? When? How?* at the Austrian Fall Meeting of the Working Groups on Andrology and Oncology (Krems, Austria)
- Jun 2011 Presentation of actual data on prognostic factors for 1st and 2nd line chemotherapy in bladder cancer and presentation of JASINT IN213 study at the German Society of Urology (DGU), Academy of German Urologists (ADU) and German Cancer Society (DKG) Symposium on Advanced Bladder Cancer (Düsseldorf, Germany)
- May 2011 *New prognostic factors in testicular cancer treatment* and *Target treatment of RCC* at the Austrian Association of Haematology and Oncology (OeGHO) Spring Meeting and Working Group on Hemato-Oncological Nursing Meeting (Pörtschach, Austria)
- Oct 2010 *Systemic treatment of advanced urothelial cancer* at the International Educational Conference (MediPage) ASCO perspectives of oncology development (Warsaw, Poland)
- May 2010 *Management of elderly and/or frail bladder cancer patients* and discussant at the Pomeranian Uro-Oncology Meeting *Oncoforum on Multidisciplinary Treatment of Bladder Cancer* (Jastrzebia Gora, Poland)
- Apr 2010 *Metastatic bladder cancer therapy* at the German Working Group on Internal Oncology (AIO) Genitourinary Cancers Meeting (Hamburg, Germany)
- Nov 2009 Presentation of a uniform follow-up concept (as clinical guideline and for prospective data acquisition) at the German Working Group on Internal Oncology (AIO) GU Cancers Meeting (Berlin, Germany)
- Sep 2009 *Tumour treatment for elderly: medical therapy* at the Congress of the German Society of Urology (Dresden, Germany)
- Jun 2009: *Indications for perioperative chemotherapy of advanced and metastatic cancers and Palliative methods: What is best supportive care?* at the Austrian Urologic Oncology Working Group (AUO), German Working Group on Radiologic Oncology (ARO) and German Working Group on Internal Oncology (AIO) Symposium on advanced bladder cancer (Düsseldorf, Germany)
- Apr 2009 *Selecting optimal therapy in patients unfit for CDDP frontline therapies and Skeletal-related events and their management in prostate cancer* at the Annual European Perspectives in Genitourinary Oncology (Barcelona, Spain)
- 2008 Presentations at 3 Austrian Urologic Oncology Working Group (AUO) Meetings (Austria-wide)
- Sep 2008 *Exposure to radiation and follow-up treatment* at the German Testicular Cancer Study Group Meeting at German Urology Association (DGU) Congress (Stuttgart, Germany)
- May 2008 Chair of the session *Diagnostic measures for staging and presentation The role of PET after chemotherapy* at the ESMO Symposium on Testicular Cancer and International Consensus Meeting on Testicular Cancer (Munich, Germany)
- Jun 2007 *Advanced renal cell carcinoma: diagnostics, frequent symptoms and their treatment, metastases surgery, immunotherapy, modern therapy* at Young Urology Uro-Oncologic Curriculum on Renal Cell Cancer (Salzburg, Austria)

- Sep 2006 Presentation on bone metastases (sponsored by Novartis) at the breast cancer patient advocacy group (Eisenstadt, Austria)
- Apr 2006 Presentation on systemic therapy of testicular cancer at the Austrian Association of Haematology and Oncology (OeGHO) Spring Meeting (Wels, Austria)
- Jun 2005 *Proof of disseminated tumour cells/micro metastases: methods and consequences* and *Circulating tumour cells in germ cell tumours: Evidence by an automatic microscope technique (a pilot project)* at the 2nd Dresden Workshop on *Evidence of disseminated tumour cells and micrometastases: methods and consequences* (Dresden, Germany)
- May 2005 Presentation for the South-Eastern German Association of Urology Meeting: CTCs in testis cancer.
- Feb 2005 *Biophosphonates in bone metastases and osteoporosis treatment* at a prostate cancer patient advocacy group session (Vienna, Austria)
- Nov 2004 *Oncological prostate cancer trials* at a prostate cancer self-help group session (Vienna, Austria)
- Sep 2001 *SEMPET – Predictive impact of FDG PET for post-chemotherapy residual masses in bulky seminoma patients* at the International Germ Cell Tumour Conference (Leeds, UK)

CLINICAL TRIALS

Chief Investigator

As chief investigator I have been involved in developing ideas, protocol writing, amendments, approval process, study conduct, recruitment and publication (if applicable)

1. Global chief Investigator: BCG with or without Durvalumab in patients with high risk non-muscle invasive bladder cancer: Three-arm randomised phase III trial (**POTOMAC trial**) NCT03528694
2. **Urothelial Cancer Study JASINT1**
Randomised phase II study assessing the combination of vinflunine with gemcitabine and vinflunine with carboplatin in patients ineligible for cisplatin with advanced or metastatic transitional cell carcinoma of the urothelium. (published)
3. **EORTC 30986**
Randomised phase II/III study assessing Gemcitabine/Carboplatin and Methotrexate/Carboplatin/Vinblastine in previously untreated patients with advanced urothelial cancer ineligible for Cisplatin-based chemotherapy. (published)
4. **LBI-ACR VIEnna Protocol N°001, CESAR Protocol N° 001, CESAR-Nr.: C-I-001**
Combined chemo-radiotherapy with Gemcitabine in patients with locally advanced inoperable transitional cell carcinoma (TCC) of the urinary bladder and/or in patients ineligible for operation: A multicentre phase I trial.
5. **Translational research study in bladder cancer / cooperation with Institute for Tumour Biology University Hamburg Eppendorf**
Circulating tumour cells in bladder cancer patients relapsing after or refractory to platinum-based first line chemotherapy. (finished accrual, analysed, manuscript in preparation)
6. In set up – Medical Oncology PI:
Rad-IO Trial: A multi-arm multi-stage randomised trial of strategies for improving outcomes with chemoradiotherapy with 5FU and mitomycin C in patients with T2-T4aN0M0 muscle-invasive bladder cancer undergoing primary radical therapy

National Coordinator

7. **UK national coordinator and PI: Incyte-study:** A Phase 2, Open-label, Single Agent, Multi-Center Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects with Metastatic or Surgically Unresectable Urothelial Carcinoma Harboring FGF/FGFR Alterations; Protocol No.: INCB54828-201
8. **Austrian National coordinator and PI:** An open-label study of Sipuleucel T in European men with metastatic, castrate resistant prostate cancer (P11-1)
9. **Austrian national coordinator and PI: SWITCH-2-trial, EudraCT-Nr.: 2011-004396-36**
Phase III randomised sequential open-label study to evaluate the efficacy and safety of Sorafenib followed by Pazopanib versus Pazopanib followed by Sorafenib in the treatment of advanced/metastatic renal cell carcinoma. (to be presented at ESMO 2017)

Past and present genitourinary cancer study experience, principal investigator or national coordinator

1. FIDES-02: An Open-label Multi-cohort Phase 1b/2 Study of Derezantinib and Atezolizumab in Patients With Urothelial Cancer Expressing Activating Molecular FGFR Aberrations; NCT04045613
2. MK-3475-866 / KEYNOTE 866 Peri-operative Pembrolizumab + Neoadjuvant Chemotherapy vs Periop. Placebo + Neoadjuvant Chemotherapy in Cisplatin Eligible Patients with Muscle-Invasive Bladder Cancer
3. NKTR-214 Eine randomisierte, nicht vergleichende, unverblindete Studie der Phase 2 zu NKTR-214 in Kombination mit Nivolumab und zu Chemotherapie bei Patienten mit lokal fortgeschrittenem oder metastasierendem Urothelkarzinom mit niedriger PD-L1-Expression, die für eine Cisplatin-Therapie nicht geeignet sind
4. MK-3475-641 A Phase III, randomized, double-blind Trial of Pembrolizumab (MK-3475) plus Enzalutamide vs Placebo plus Enzalutamide in Patients with metastatic Castration-Resistant Prostate Cancer
5. MK-3475-921 A Phase III, Randomized, Double-blind Study of Pembrolizumab (MK-3475) plus Docetaxel vs. Placebo plus Docetaxel in Patients with Metastatic Castration-resistant Prostate Cancer (mCRPC)
6. MK-7339-010 A Randomized, Open-Label, Phase 3 Trial of Pembrolizumab (MK-3475) in Combination with Olaparib vs Alternative Next-Generation Hormonal Therapy (NHT) in Unselected Participants with Metastatic Castration resistant Prostate Cancer (mCRPC) Progressing after NHT and Chemotherapy
7. TRITON 2 CO-338-052 A Multicenter, Open-label Phase 2 Study of Rucaparib in Patients with Metastatic Castration-resistant Prostate Cancer Associated with Homologous Recombination Deficiency
8. TRITON 3 CO-338-063 A Multicenter, Randomized, Open label Phase 3 Study of Rucaparib versus Physician's Choice of Therapy for Patients with Metastatic Castration resistant Prostate Cancer Associated with Homologous Recombination Deficiency
9. CANTATA: A Randomized, Double-Blind, Placebo-Controlled Phase 2 Clinical Trial Comparing CB-839 in Combination With Cabozantinib (CB-Cabo) vs. Placebo With Cabozantinib (Pbo-Cabo) in Patients With Advanced or Metastatic Renal Cell Carcinoma (RCC)
10. BCG with or without Durvalumab in patients with high risk non-muscle invasive bladder cancer: Three-arm randomised phase III trial (POTOMAC trial)
NCT03528694 Study of Rucaparib in Patients With Metastatic Castration-resistant Prostate Cancer and Homologous Recombination Gene Deficiency (TRITON2): NCT02952534
11. A Phase 2, Open-Label, Single-Agent, Multicenter Study to Evaluate the Efficacy and Safety of INCB054828 in Subjects With Metastatic or Surgically Unresectable Urothelial Carcinoma Harboring FGF/FGFR Alterations. NCT02872714

12. A Multicenter, Open-label, Randomized, Phase 3 Trial to Compare the Efficacy and Safety of Lenvatinib in Combination With Everolimus or Pembrolizumab Versus Sunitinib Alone in First-Line Treatment of Subjects With Advanced Renal Cell Carcinoma (CLEAR). NCT02811861

Completed trials

1. COMET-1-Study
Randomised phase III: Efficacy of Cabozantinib (XL184) versus Prednisone in castration-resistant prostate cancer (COMET-1): Evaluation of overall survival.
2. EORTC N° 30983
Randomized Phase II/III Study to Compare Taxol®-BEP versus BEP in patients with intermediate prognosis germ cell cancer.
3. EORTC-GUCG N° 30974
Randomisierte Phase III Studie zum Vergleich einer sequentiellen Hochdosis mit Cisplatin/Etoposid/Ifosfamid und Stammzell-Unterstützung versus BEP bei Patienten mit Keimzelltumoren schlechter Prognose.
4. EORTC N° 30994
Randomisierte Phase III-Studie: Vergleich sofortiger adjuvanter Chemotherapie versus verzögerter Chemotherapie bei Rezidiv nach radikaler Zystektomie bei Patienten mit Übergangszellkarzinom der Harnblase (Stadium: pT3-pT4 und/oder N+M0).
5. EORTC N° 30021 AVENTIS PHARMA Protocol AVE3139E/2501
Randomisierte Phase II Studie mit Docetaxel (Taxotere®) und Oblimersen (Antisense Oligonucleotid gerichtet gegen bcl-2) versus Taxotere alleine bei Patienten mit hormonrefraktärem Prostatakarzinom.
6. CA 18 3001
A phase II study of intravenous Vinflunine (IV) in patients with locally advanced or metastatic transitional cell carcinoma (TCC) of the urothelium.
7. TOPAS
Multizentrische Phase II Studie zur intermittierenden Behandlung mit Docetaxel und Prednisolon bei Patienten mit einem asymptomatischen hormonrefraktärem Prostatakarzinom.
8. *Multicentric non-randomized open phase-II-Studie with TKI258 for patients with advanced urothelial cancer with mutated or wild type FGFR-3.*
9. NCT00732914 SWITCH
Phase III randomised sequential open-label study to evaluate efficacy and safety of Sorafenib (SO) followed by Sunitinib (SU) versus Sunitinib followed by Sorafenib in patients with advanced/metastatic renal cell carcinoma without prior systemic therapy.

Phase I trial experience

1. *An open-label, Phase I, dose-escalation study to characterize the safety, tolerability, pharmacokinetics, and maximum tolerated dose of BAY 2010112 given once daily by subcutaneous administration in subjects with castration-resistant prostate cancer.* (ongoing)
2. Clinical Trial Protocol CBGJ398X2101 – Phase I – first in human
A phase I, open-label, multi-center, dose escalation study of oral BGJ398, a pan FGFR kinase inhibitor, in adult patients with advanced solid malignancies (ongoing)
3. LBI-ACR VIEnna Protocol N°001, CESAR Protocol N° 001, CESAR-Nr.: C-I-001.
Combined chemo-radiotherapy with Gemcitabine in patients with locally advanced

inoperable transitional cell carcinoma (TCC) of the urinary bladder and/or in patients ineligible for operation: A multicentre phase I trial.

4. N° E7070-E044-210
Offene Studie zur Dosisfindung von E7070 in Kombination mit Carboplatin und Phase II-Studie bei Patienten mit lokal fortgeschrittenem/metastasiertem Nicht – kleinzelligem Lungenkarzinom (Stadium IIIb/IV).
5. Phase I – *Dosis-Eskalationsstudie mit Natrium trans- [tetrachlorobis(1H-indazol)ruthenat(III)] / Indazolhydrochlorid (1:1.1) oder FFC14A (akzeleriertes Titrationsdesign) bei Patienten mit soliden Tumoren.*
6. ML 20784 REBECA
Phase I Studie von Erlotinib (Tarceva), Bevacizumab (Avastin) und Capecitabin (Xeloda) bei Patienten mit fortgeschrittenem, nicht-resektablen und/oder metastasiertem Pankreaskarzinom.

International Studies - Steering Committee Member

1. KEYNOTE 057: A PHASE II, UNBLINDED, OPEN-LABEL, CLINICAL TRIAL TO STUDY THE EFFICACY AND SAFETY OF PEMBROLIZUMAB (MK-3475) IN SUBJECTS WITH HIGH RISK NON-MUSCLE INVASIVE BLADDER CANCER (NMIBC) UNRESPONSIVE TO BACILLUS CALMETTE-GUERIN (BCG) THERAPY (MK-3475 057)
2. ONC-MA-1001 Global Prostate Cancer Observational Study
A prospective, longitudinal, multinational, observational study to describe patterns of care and outcomes of men who are at high risk for poor clinical outcomes after experiencing biochemical failure definitive prostate cancer therapy, men with castration-resistant prostate cancer and men with metastatic prostate cancer at initial diagnosis (sponsored by Astellas Global Medical Affairs, Inc.).
3. 9785-MA-1002 European Observational Study with Enzalutamide in mCRPC
A European prospective observational cohort study assessing the outcomes associated with Enzalutamide treatment in patients with metastatic castration resistant prostate cancer (mCRPC) (sponsored by Astellas Global Medical Affairs, Inc.).
4. IDMC chair Roche (SAUL): AN OPEN LABEL, SINGLE ARM, MULTICENTER, SAFETY STUDY OF ATEZOLIZUMAB IN LOCALLY ADVANCED OR METASTATIC UROTHELIAL OR NON-UROTHELIAL CARCINOMA OF THE URINARY TRACT
PROTOCOL NUMBER: MO29983
5. Phase 3, randomized, double-blind trial of pembrolizumab plus epacadostat or placebo for cisplatin-ineligible urothelial carcinoma (UC): KEYNOTE-672/ECHO-307.
6. IMvigor130: A randomized, Phase III study evaluating first-line (1L) atezolizumab (atezo) as monotherapy and in combination with platinum-based chemotherapy (chemo) in patients (pts) with locally advanced or metastatic urothelial carcinoma (mUC).
7. Rad-IO Trial: A multi-stage randomised trial of synchronous and adjuvant durvalumab (Medi4736) with chemoradiotherapy with 5FU and mitomycin C in patients with T2-T4aN0M0 muscle-invasive bladder cancer undergoing primary radical therapy

International and national study participation (Sub-investigator) since 2004

1. TITAN-RCC: A Phase II Single Arm Clinical Trial of a Tailored ImmunoTherapy Approach With Nivolumab in Subjects With Metastatic or Advanced Renal Cell Carcinoma; NCT02917772 (GER)
2. STAMPEDE (UK)
3. iMVIGOR010 (UK)
4. MK-361 (UK)
5. CAB-B1 (UK)
6. EMBARK (UK)
7. PROSPER (UK)
8. POUT (UK)
9. NEOBLADE (UK)
10. ACIS (UK)
11. TUXEDO (UK)
12. SOTIO - VIABLE (UK)
13. TAK-700 – Protocol C21005, EK 10-174-1010, Eudract Nr. 2010-018662-23
A phase 3, randomised, double-blind, multicentre trial comparing TAK-700 plus prednisone with placebo plus Prednisone in patients with metastatic castration-resistant prostate cancer that has progressed following taxane-based therapy (sponsored by Millenium).
14. TAK-700 – Protocol C21004, EK 10-173-1010, Eudract Nr. 2010-018661-35
A phase 3, randomised, double-blind, multicentre trial comparing Orteronel (TAK-700) plus Prednisone with placebo plus Prednisone in patients with chemotherapy-naïve metastatic castration-resistant prostate cancer (sponsored by Millenium).
15. EORTC N° 16011-26013
Offene Phase II-Studie mit STI571 (Glivec®) als täglich orale Gabe bei Patienten mit Gliomen.
16. EORTC-GCCG N° 55971
Randomisierte Phase III Studie: Vorangegangene volumsverkleinernde Operation versus neo-adjuvante Chemotherapie bei Patientinnen mit epithelialem Ovarialkarzinom im Stadium IIIC oder IV.
17. EORTC-IDBBC-ECSG-PAMM Group N° 10993
Randomisierte Phase II Studie über zwei verschiedene Dosierungsschemata von Caelyx® bei metastasiertem Brustkrebs, die entweder älter als 65 Jahre sind, oder die Standardtherapie mit Anthracyclin zurückweisen.
18. NCIC CTG N°OV. EORTC-GCG N°55012
Phase III Studie mit Cisplatin plus Topotecan gefolgt von Paclitaxel plus Carboplatin versus Paclitaxel plus Carboplatin als first-line Chemotherapie bei Patientinnen mit Erstdiagnose eines fortgeschrittenen epithelialen Ovarialkarzinoms.
19. EORTC N° 55994
Randomisierte Phase III Studie: Neoadjuvante Chemotherapie gefolgt von Operation versus gleichzeitige Radiotherapie und Chemotherapie bei Patientinnen mit Zervixkarzinom FIGO Ib2, IIa>4cm ODER IIb.
20. Protocol MREC (1)
Multizentrische randomisierte kontrollierte Therapiestudie zum Vergleich einer durch Tumorchemosensitivitätsanalyse gesteuerten Chemotherapie mit einer vom behandelnden Arzt ausgewählten Therapie bei Patientinnen mit rezidiviertem Platin-resistenten Adenokarzinom des Ovars.
21. EORTC N° 40012 - PETACC-4
97/25 Randomisierte Phase III Intergroup Studie bei Patienten mit reseziertem Kolonkarzinom im Stadium II (Dukes B): 6-monatige Infusionen mit 5-FU, CPT-11 (± Folsäure) versus Beobachtung. Bestimmung von biologischen prädiktiven und Response-Faktoren.
22. EORTC 55041 - AGO 009
Randomisierte, multizentrische Phase III Studie zum Vergleich von Erlotinib versus Beobachtung bei Patientinnen mit epithelialem Karzinom der Ovarien, des eritoneums oder der Tuben ohne Nachweis einer Krankheitsprogression nach platinhaltiger First-Line-Chemotherapie bei Stadium I (bei hohem Risiko) und Stadium II – IV.
23. ALIMTA (LY 231514) H3E-MC-JMDV
Kombinierte Phase I/II Studie mit ALIMTA und Cyclophosphamid, alle 21 Tage verabreicht, bei Patienten mit lokal fortgeschrittenem oder metastasiertem Brustkrebs.
24. Protocol M66001
Offene Phase 3 Studie zum Vergleich von Xeloda (Capecitabine) mit i.v. Bolus 5-Fluorouracil in Kombination mit niedrig-dosiertem Leucovorin als adjuvante Chemotherapie bei Patienten nach Operation eines Kolonkarzinoms Stadium Dukes C.
25. ECTO – I
Europäische Vergleichsstudie von primärer Chemotherapie und primärer Operation bei Patientinnen mit operablem Brustkrebs (> 2cm): Adjuvant Doxorubicin gefolgt von CMF vs. Adjuvant Doxorubicin / Paclitaxel gefolgt von CMF vs. Neoadjuvant Doxorubicin / Paclitaxel gefolgt von CMF.
26. N° E7070-E044-210
Offene Studie zur Dosisfindung von E7070 in Kombination mit Carboplatin und Phase II-Studie bei Patienten mit lokal fortgeschrittenem/metastasiertem Nicht – Kleinzelligem Lungenkarzinom (Stadium IIIb/IV).
27. LIGAND PHARMACEUTICALS INC Protocol L 1069-48
Randomisierte Phase III- Studie mit Targretin® Kapseln /Carboplatin/ Paclitaxel versus Carboplatin/ Paclitaxel bei Patienten mit nicht vorbehandeltem, lokal fortgeschrittenem oder metastasiertem Nicht-kleinzelligem Lungenkarzinom.
28. EMR 62 202-021

Offene, nicht kontrollierte, multizentrische, Phase I/II- Studie zur Bestimmung der Anwendungssicherheit und Wirksamkeit von Cetuximab in Kombination mit 5-FU/Leukovorin plus wöchentlich Oxaliplatin (FUFOX) bei Patienten mit Epidermal Growth Factor Receptor (EGFR) – positivem, fortgeschrittenem kolorektalem Karzinom.

29. Protocol GI –C 0014-32 W-AR 3066-K1-203-EU
Randomisierte, offene Phase II-Studie von zwei Dosierungsstufen von CCI-779, mit wöchentlicher i.v.Gabe, bei Patientinnen mit lokal fortgeschrittenem und /oder metastasiertem Brustkrebs.
30. N° 20020408, BB-IND 8382
Offene, randomisierte Phase 3 Studie von ABX-EGF und supportiver Therapie im Vergleich zu rein supportiver Therapie bei Patienten mit metastasiertem kolorektalem Karzinom.
31. Protocol N° 20030194
Multizentrische, offene, einarmige Studie zur Bestimmung der Anwendungssicherheit von fortgesetzter ABX-EGF-Therapie bei Patienten mit metastasiertem kolorektalem Karzinom (Amgen).
32. BAY 43-9006 CESAR Protocol N° C-II-001
Phase II Studie mit BAY 43-9006 bei Patienten mit lokal-fortgeschrittenem und/oder metastasiertem: Hormon-refraktärem Prostatakarzinom (C-II-001/1), Pankreaskarzinom (C-II-001/2), Nicht-kleinzelligem Lungenkarzinom (C-II-001/3).
33. Phase I – Dosis-Eskalationsstudie mit Natrium trans- [tetrachlorobis(1H-indazol)ruthenat(III)] / Indazolhydrochlorid (1:1.1) oder FFC14A (akzeleriertes Titrationsdesign) bei Patienten mit soliden Tumoren.
34. MO18024
Randomisierte, offene, multizentrische Phase II Studie zur Untersuchung der Wirksamkeit und Sicherheit von zwei Dosierungsstufen des intravenös applizierten humanen monoklonalen Antikörpers MT201, bei Patientinnen mit metastasiertem Mammakarzinom MT201-202 Erstlinien-Therapie mit Bevacizumab und Chemotherapie im metastasierten Karzinom des Kolons oder Rekums: „First BEAT“ (Bevacizumab Expanded Access Trial).
35. CRYSTAL, EMR 62 202-013
Offene, randomisierte, kontrollierte multizentrische Phase III-Studie mit 5-FU/FA plus Irinotecan und Cetuximab im Vergleich mit 5-FU/FA plus Irinotecan als Erstlinien-Behandlung bei Patienten mit EGF-Wachstumsfaktorrezeptor (Epidermal Growth Factor Receptor) exprimierendem metastasierendem Kolorektalkarzinom.
36. Protocol 20030205
Randomisierte, multizentrische, doppelblinde, placebokontrollierte Dosisfindungsstudie von subkutan verabreichtem AMG 114 zur Behandlung einer Anämie bei Patienten mit nicht-myeloischen malignen Erkrankungen, die eine multizyklische Chemotherapie erhalten.
37. AVANT-Study, BO17920A
Randomisierte, 3-armige, multinationale Phase III Studie zur Untersuchung von Bevacizumab (q3w oder q2w) in Kombination mit Capecitabine plus Oxaliplatin (XELOX)(q3w) oder Fluorouracil/Leukovorin mit Oxaliplatin (FOLFOX-4) versus FOLFOX-4 Regime allein als adjuvante Chemotherapie bei Kolonkarzinom.
38. EMR 62 202-002
EXTREME cetuximab (Erbitux®) in Kombination mit Cisplatin oder Carboplatin und 5_Fluorouracil zur First-line-Therapie bei Probanden mit rezidivierendem und/oder metastasierendem Plattenepithelkarzinom des Kopfes oder Halses.
39. IGN101/2-03
Multizentrische, offene, Phase II Studie zur Bestimmung der Sicherheit, Verträglichkeit, Immunogenität und Wirksamkeit von multiplen subkutanen Impfungen mit IGN101 auf disseminierte Tumorzellen bei Patienten mit Ep-CAM exprimierenden Karzinomen.
40. CRAD 001 C2222
Phase 2, doppel-blinde, randomisierte, plazebo-kontrollierte, multizentrische Studie zur Beurteilung einer Zusatztherapie mit RAD001 zu Letrozol (Femara®) bei der präoperativen Behandlung von primärem Brustkrebs bei postmenopausalen Frauen.
41. EMR 2000 20-034 MAURICE
Offene, einarmige, multizentrische Studie der Phase II mit Matuzumab in Kombination mit Irinotecan-haltiger Basis-Chemotherapie bei Patienten mit den epidermalen Wachstumsfaktorrezeptor exprimierendem metastasierenden Kolorektalkarzinom, die während der Therapie oder innerhalb von vier Wochen nach Beendigung der Irinotecan-haltigen Basis-Chemotherapie Krankheitsprogression zeigten.
42. ECTO II, FM-B04-01
Europäische Vergleichsstudie von primärer systemischer Therapie bei Patientinnen mit operablem Brustkrebs und T > 2cm.
43. Pfizer A 6181036
Ein Behandlungsprüfplan für Patienten mit gastrointestinalen Stromatumoren, die an anderen klinischen Prüfungen mit SU011248 nicht teilnehmen können und auf Imatinibmesylat nicht ansprechen oder es nicht vertragen.
44. N° 309544
A prospective, multicentre, randomised, parallel-group, open-label phase II study to investigate the efficacy, safety and tolerability of 2 doses of ZK 219477 (16 and 12 mg/m² body surface area) in patients with metastatic breast cancer.
45. SB-497115/003
Doppelblinde, randomisierte, multizentrische, plazebokontrollierte Parallelgruppen-Dosisfindungsstudie zur Bewertung der Wirksamkeit, Sicherheit und Pharmakokinetik des oralen Thrombopoietin-Rezeptoragonisten (SB-497115-GR) mit 50 mg, 75 mg und 100 mg bei Patienten mit soliden Tumoren, die mehrere Chemotherapiezyklen erhalten.
46. 6181064
Randomisierte Phase III Studie von Docetaxel in Kombination mit Sunitinib versus Docetaxel, in der Erstlinientherapie bei Patientinnen mit fortgeschrittenem Brustkrebs.
47. AMG 20050181

Randomisierte, multizentrische Phase III Studie zum Vergleich der Wirksamkeit von Panitumumab in Kombination mit Chemotherapie und Chemotherapie allein bei Patienten mit vorbehandeltem, metastasiertem Kolorektalkarzinom.

48. BI 1216.10
Offene, randomisierte klinische Phase II Studie bei Patienten mit nicht-resezierbarem fortgeschrittenem Pankreaskarzinom zur Bestimmung der Wirksamkeit, Sicherheit und Pharmakogenetik von BI 2536, gegeben als i.v. Dosis von einmalig 200 mg oder 60 mg täglich an drei aufeinanderfolgenden Tagen, jeweils wiederholt alle drei Wochen.
49. CO328T07
Multizentrische, offene, randomisierte Phase II Studie von CNTO 328, einem monoklonalem Anti-Interleukin-6 Antikörper, in Kombination mit Mitoxantron im Vergleich zu Mitoxantron allein bei patienten mit hormonrefraktärem, metastasiertem Prostatakarzinojm (HRPC).
50. H3E-MC-S102
Phase II Studie mit Pemetrexed im Vergleich zu Pemetrexed plus Erlotinib als Zweitlinienbehandlung von nicht kleinzelligem Lungenkrebs.
51. H6Q-MC-JCBF
Randomisierte Phase 3-Vergleichsstudie von Enzastaurin und Lomustin zur Behandlung des rezidivierenden intrakraniellen Glioblastoma Multiforme.
52. D8480C00013, HORIZON III
Randomisierte, doppelblinde, multizentrische Phase II/III Studie zum Vergleich der Wirksamkeit von AZD2171 in Kombination mit 5-Fluorouracil, Leucovorin und Oxaliplatin (FOLFOX) mit der Wirksamkeit von Bevacizumab in Kombination mit FOLFOX bei Patienten mit bisher nicht vorbehandeltem metastasierendem Kolorektalkarzinom.
53. L00070 IN 303 BO VICTORIA
Phase III Studie mit Vinflunine plus Gemcitabine versus Paclital plus Gemcitabine bei Patientinnen mit inoperablem, lokal fortgeschrittenem oder metastasiertem Brustkrebs nach vorangegangener Anthrazyklin-basierter adjuvanter Chemotherapie.
54. OPERA
Oxaliplatin und Cetuximab in der Erstlinien-Behandlung des mKRK. Offene, nicht-kontrollierte, multizentrische Phase II Studie zur Untersuchung von 5-FU/FA plus Oxaliplatin (FOLFOX-4) plus Cetuximab in der Erstlinien-Behandlung des metastasierten kolorektalen Karzinoms bei Patienten mit nicht-detektierbaren EGF-Rezeptor.
55. VEG 105192
Randomisierte, doppelblinde, placebo-kontrollierte multizentrische Studie der Phase III zur Untersuchung der Wirksamkeit und Sicherheit von Pazopanib (GW786034) im Vergleich zu Placebo bei Patienten mit lokal fortgeschrittenem und/oder metastasierendem Nierenzellenkarzinom, bei denen die Erkrankung nach einer ersten Behandlung mit Zytokinen fortgeschritten ist.
56. VEG 107769
Offene Erweiterungsstudie der Phase III zur Untersuchung der Wirksamkeit und Sicherheit von Pazopanib (GW786034) bei Patienten mit Nierenzellkarzinom, die an der klinischen Prüfung VEG105192 teilgenommen haben.
57. Schering 309821
Randomisierte Phase-II-Studie zur Untersuchung der Wirksamkeit, Sicherheit und Verträglichkeit von ZK 230211 (25 mg versus 100 mg) als Second-Line-Hormontherapie bei postmenopausaken Frauen mit hormonrezeptorpositivem metastasierten Mammakarzinom.
58. WO 20697 A; NEOSPHERE
Randomisierte, multizentrische, multinationale Phase II Studie zu Trastuzumab plus Docetaxel versus Trastuzumab plus Docetaxel plus Pertuzumab versus Trastuzumab plus Pertuzumab bei Patientinnen mit lokal fortgeschrittenem, entzündlichem oder sich im Frühstadium befindlichen HER2 positivem Brustkrebs.
59. AMG 386 20060439
Randomisierte, doppel-blinde, multizentrische , Phase 2 Studie zur Beurteilung der Wirksamkeit und Verträglichkeit von Cisplatin & Capecitabine (CX) in Kombination mit AMG 386 oder Placebo bei Patienten mit metastasiertem Adenokarzinom des Magens-, des gastroösophagealen Überganges- oder der distalen Speiseröhre.
60. ADVANTAGE, EMR 200052-013
Open-label, randomised phase I/II study of Cilengitide to evaluate the safety and efficacy of the combination of different regimens of Cilengitide added to Cisplatin, 5-FU and Cetuximab in subjects with recurrent/metastatic squamous cell cancer of the head and neck.
61. BI 1257.1
Offene Dosisescalationsstudie zur Untersuchung von zwei Dosierungsschemata mit BI 831266 verabreicht als intravenöse 24-Stunden-Dauerinfusion bei Patienten mit fortgeschrittenen Tumorerkrankungen.
62. MK 0646-004
Klinische Studie zur Untersuchung von MK-0646 bei Anwendung gemeinsam mit Cetuximab und Irinotecan bei Patienten mit metastasiertem Kolorektalkarzinom.
63. ML 20784 REBECA
Phase I Studie von Erlotinib (Tarceva), Bevacizumab (Avastin) und Capecitabin (Xeloda) bei patienten mit fortgeschrittenem, nicht-resektablen und/oder metastasiertem Pankreaskarzinom.
64. TDM4450g
Randomisierte, multizentrische Phase II Studie zur Wirksamkeit und Sicherheit von Trastuzumab-MCC-DM1 gegen Trastuzumab und Docetaxel, bei Patienten mit Her2-positivem Brustkrebs, die keine Chemotherapie für die metastasierte Erkrankung bekommen haben.

INVITED SPEAKER FOR PHARMACEUTICAL COMPANIES

2005- Present Numerous presentations at meetings, launch events and symposia nationally and internationally for the pharmaceutical industry:
Amgen, Astellas, Bayer, BMS, Celgene, Dendreon, Eli Lilly, Essa, Ferring, GlaxoSmithKline, Ipsen, Janssen, Merck, MSD, Novartis, OncoGenex, Pfizer, Pierre Fabre Oncologie, Roche, Sanofi Aventis, Shionogi, Synthon, Takeda, Teva

Recent International Activities and Advisory Boards for Drug and Trial Development Hosted by Pharmaceutical Companies

Amgen

Nov 2017 Advisory Board (Madrid, Spain)

Astellas

Oct 2017 Invitation by the Kingdom of Saudi Arabia Urology Association for Enzalutamide Launch Event (Riad, Kingdom of Saudi Arabia)
May 2017 Advisory Board on Enfortumab Vedotin (Amsterdam, the Netherlands)
Oct 2016 Member of Astellas ASPIRE Steering Committee meeting (Copenhagen, Denmark)
Feb 2015 Academic faculty co-chair of Astellas Bladder Cancer Discovery Group Meeting (Amsterdam, the Netherlands)
Nov 2014 Member of Astellas Advisory Board (Salzburg, Austria)
Nov 2014 Member of Astellas Advisory Board (Vienna, Austria)
Oct 2014 Presentation on mCRPC at Xtandi Launch Symposium (Vienna, Austria)
Aug 2014 Member of Astellas Global Oncology Portfolio Advisory Board (Melbourne, Australia)
Jun 2014 Presentation of details on metastatic prostate cancer treatment with Xtandi at the Astellas Xtandi Round Table Meeting (Vienna, Austria)
May 2014 Presentation on the therapeutic landscape of mCRPC, patient cases and AFFIRM and PREVAIL studies at 3 Astellas International Xtandi Advisory Boards (Dubai, United Arab Emirates)
Mar 2014 Moderation of the session *What are key therapeutic targets in prostate cancer? Updates on the pathophysiology of prostate cancer from ASCO GU 2014* at Astellas Changing Tomorrow in Oncology Meeting (Barcelona, Spain)
Mar 2014 Chair and presentation *Enzalutamide in men with chemotherapy-naïve mCRPC: Results of the Phase 3 PREVAIL Study* at Astellas Xtandi Advisory Board (Semmering, Austria)
Feb 2014 Member of Astellas Pan-European Uro-Oncology Expert Meeting (Milan, Italy)

AstraZeneca

Jun 2017 Scientific Lunch (Chicago, USA)
Feb 2017 Advisory Board NMIBC (Orlando, USA)
Oct 2016 Advisory Board Bladder Cancer (Copenhagen, Denmark)

Bayer

Oct 2016 Member of Bayer mCRPC Advisory Board (Paddington, UK)
Nov 2015 Member of Bayer Radium 223 Advisory Board (Barcelona, Spain)
Apr 2014 Member of Bayer Radium 223 for mCRPC Expert Panel (Vienna, Austria)
Jan 2014 Member of Bayer Xofigo Advisory Board (San Francisco, CA, USA)

Bristol-Myers Squibb

Mar 2017 Member of BMS Advisory Board (London, United Kingdom)

Celgene

Dec 2013 Member of Celgene Advisory Board (Zürich, Switzerland)

Dendreon

Sep 2014 Dendreon Advisory Board (Madrid, Spain)

Eisai Inc.

Jan 2016 Member of Eisai Inc. Eribulin Ph3 Urothelial Advisory Board (San Francisco, IL, USA)

ESSA

Sep 2015 Member of ESSA Advisory Board: EPI-506 clinical development plan (Vienna, Austria)

Ferring

Sep 2017 Advisory Board (Amsterdam, the Netherlands)

Jun 2016 Advisory Board (New York, USA)

Ipsen

Oct 2016 Advisory Board (Copenhagen, Denmark)

Jun 2014 Tasquinimod Post AA/Enz Phase II Study Steering Committee Meeting (Paris, France)

GSK

Sep 2014 Advisory Board (Vienna, Austria)

Janssen

2016-2017 Multiple local educational meetings (Birmingham, Harborn, Nottingham, Coventry, UK)

Oct 2017 Participation in Janssen Prostate Cancer Debate (Berlin, Germany)

Jun 2017 Participation in Janssen Expert Dinner (Chicago, USA)

May 2017 Janssen Evening Talk (Birmingham, UK)

Mar 2017 Faculty member at the Janssen Prostate Cancer Summit (London, UK)

Feb 2016 Faculty member at the Janssen Prostate Cancer Summit (London, UK)

Jan 2016 Scientific committee member at the Janssen ASCO GU DIRECT Meeting and Broadcasting (San Francisco, IL, USA)

Oct 2015 Faculty member at Janssen Prostate Cancer Debate (Lisbon, Portugal)

Sep 2015 Faculty member and chair at the Janssen Prostate Cancer Forum (Vienna, Austria)

Apr 2015 Participation in Janssen Lecture Dinner (Salzburg, Austria)

Jan 2015 Participation in Janssen Prostate Cancer Debate (Vienna, Austria)

Oct 2014 Presentation of experience with Zytiga and case studies at Janssen Zytiga Innovation Circle (Mondsee, Austria)

Sep 2014 Chair of Janssen Lecture Dinner (Madrid, Spain)

Jul 2014 *Are we on the way to identifying the 1st predictive marker in mCRPC at the Janssen Prostate Cancer TASC Meeting (Amsterdam, Netherlands)*

Jun 2014 Member of Janssen Advisory Board (Vienna, Austria)

Jun 2014 Chair and moderation at the Janssen *Zytiga is now* event (Vienna, Austria)

May 2014 Participation in Janssen Prostate Cancer Current Treatment Practices Meeting (Dublin, Ireland)

May 2014 Participation in Paul Janssen Academy Project Meeting (Vienna, Austria)
Jan 2014 *Chemotherapy remains central to the management of patients with mCRPC* at the Janssen Prostate Cancer Debate Meeting (Rome, Italy)
Oct 2013 *Why chemotherapy has a role in the future management of mCRPC: overview of chemotherapy data* at the Janssen Prostate Cancer Debate Meeting (Copenhagen, Denmark)
Jun 2013 *Report of educational needs assessment in mCRPC* at the Janssen Prostate Cancer TASC Meeting (Amsterdam, Netherlands)
Jan 2011 *Evolving treatment options in castration-resistant prostate cancer* at the Janssen Prostate Cancer Debate Meeting on *Evolving treatment options in castration-resistant prostate cancer* (London, UK)
Jul 2011 *Summaries of toxicities for chemotherapy and novel anti-androgen therapies from an oncologist's perspective* at the Annual Prostate Cancer Core Faculty Meeting (Amsterdam, Netherlands)
May 2011 *Treatment options for patients with metastatic CRPC: chemotherapy* at the Janssen Prostate Cancer Faculty Update Meeting (Sophia Antipolis, France)

Merck Sharp & Dohme

Nov 2017 Advisory Board (Munich, Germany)
Feb 2017 Advisory Board (Orlando, USA)
Feb 2016 Advisory Board (Orlando, USA)
Nov 2016 GU Advisory Board (Miami, USA)
Jan 2016 Advisory Board (Madrid, Spain)
Jan 2016 Bladder Cancer Advisory Board (London, UK)

Oncogenex

Feb 2015 Member of Oncogenex Bladder Cancer Advisory Board (Orlando, USA)
Nov 2012 Member of TEVA Oncogenex Custirsen CRPC Advisory Board (London, UK)

Pierre Fabre Oncologie

2011-2017 Yearly National Symposium on Bladder cancer (Öhningen, Germany)
Nov 2015 Presentation at Pierre Fabre sponsored *Bladder Cancer Update* (St. Pölten, Austria)
Apr 2015 Summit on Difficult-to-Treat Patients with Urothelial Cacinoma (Geneva, Switzerland)
Apr 2014 Participation in Pierre Fabre Oncology Expert Meeting – Protocol development (Paris, France)

Pfizer

Mar 2017 Merck/Pfizer: Avelumab Advisoy Board on Bladder Cancer (London, UK)
Nov 2014 Member of Pfizer mRCC Advisory Board (Vienna, Austria)

Roche

Oct 2015 Member of Roche Advisory Board (London, UK)
Jan 2015 Member of Roche GO29294 Investigator Meeting (London, UK)

Sanofi Aventis

Mar 2017 Advisory Board (St. Gallen, Switzerland)
Apr 2015 Participation in Sanofi Prostate Cancer Expert Meeting (Berlin, Germany)

SeaGen International

May 2017 Advisory Board on Bladder Cancer (Zürich, Switzerland)
Oct 2016 *Futures in Oncology* Advisory Board (Copenhagen, Denmark)

Shionogi

Jul 2013 Advisory Board for Cancer Peptide Vaccine (London, UK)

Synthon

Sep 2015 Expert Meeting (Nijmegen, the Netherlands)

Takeda

Oct 2016 Workshop on high risk PCa patients at Takeda Urocylicum (St. Wolfgang, Austria)
Nov 2015 Presentation at Takeda Fall Seminar 2015 (Krems, Austria)
Oct 2015 EAU PCa Guidelines 2015 Workshop at Takeda Urocylicum (St. Wolfgang, Austria)

MEETING ORGANIZATION

- Scientific global faculty for BLADDR: global bladder cancer conference since 2017
- As ISSECAM director's board member I have been asked to join the Organising Committee and thus co-organise the Global Congress on Prostate Cancer (PROSCA) 2015 and 2016.
- I organised and chaired a one-day testicular cancer meeting in Vienna (Nov 2013)

INTERVIEWS FOR MEDICAL PRESS AND GENERAL PUBLIC

- Ecancer TV Expert Panel Discussion at Janssen Prostate Cancer Debate (Oct 2017)
- Ecancer TV Roundtable Discussion at ESMO (Sep 2017)
- ESMO LBA Press Conference Commentator (Sep 2017)
- ASCO GU direct program: scientific committee member and live discussion broadcasted from San Francisco to Austria, Germany, Belgium, Switzerland, Dubai and The Netherlands (Jan 2016)
- ESMO/ECC 2015 Interview for patients and physicians about the ASPIRE study I presented at the meeting (Sep 2015)
- European Urology UroOnco Resource Centre Video Interview: *How to treat irresectable bladder cancer?* (Sep 2014)
- prIME Oncology Educational Video Interview on the JASINT 1 Trial (Sep 2014)
- Ecancer TV Expert Panel Discussion at Janssen Prostate Cancer Debate Meeting 2014 on advances in prostate cancer: *What is the role of chemotherapy in the future management of mCRPC?* (Jan 2014)
- Ecancer TV Expert Panel Discussion at Janssen Prostate Cancer Debate Meeting 2013 on novel agents for the treatment of elderly patients with prostate cancer: Interview on influence of age and co-morbidities on treatment decisions and the importance of overall patient health¹ (Oct 2013)
- Ecancer TV Interview and chair of the panel discussion on key mCRPC abstracts presented at ASCO 2013² (Jun 2013)
- Vital Options International, The Group Room: Interviews at ESMO 2012 on *Radiologic Diagnostics in Prostate Cancer, Bladder Cancer Update at ESMO 2012* and “*Side Effects in Young Adults with Cancer Later in Life* (Oct 2012)

¹ available at <http://ecancer.org/video/2451/novel-therapies-add-to-oncologists---treatment-arsenal.php>

² available at <http://ecancer.org/video/2022/latest-on-metastatic-castration-resistant-prostate-cancer-from-asco-2013.php>

HUMANITARIAN AID PROJECTS (MEDICAL CARE)

April 1994 Humanitarian aid project for Kurds in North Iraq

May 1991 Austrian hospital in the border area between Iran and Iraq (Nagadeh, North Iran)
(public Austrian aid for the Kurds)

LANGUAGES

German (mother tongue), fluent English, basic Italian and French.
2015 IELTs Academic, English Language exam for GMC licence

Date

Signature