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MISSION STATEMENT

COMPETENCE BUILDS CONFIDENCE!

The DeCOG (Dermatologic Cooperative Oncology Group) is affiliated with the German Cancer Society (DKG) and the German Dermatologic Society (DDG). It was founded in 1990 to combine forces in the fight against skin cancer.

The DeCOG is an independent non-profit organization dedicated to an interdisciplinary and professional exchange of scientific information and the organization of projects in the field of skin cancer.

The DeCOG promotes dermatology to increase the quality of care for skin cancer patients and to establish standards for skin cancer detection and treatment.

The DeCOG carries out and collaborates in high quality clinical trials and scientific projects in skin cancer including early detection, clinical diagnosis, and therapy, as well as experimental research.

The DeCOG organizes educational events, provides materials and promotes the scientific exchange about skin cancer topics.

The DeCOG promotes collaboration and exchange of information with other medical disciplines and cancer societies.

These goals are supported by several committees of the DeCOG: The committee of clinical trials, education, translational research, clinical guidelines in dermatology, quality assurance, outpatient dermatology, skin cancer registries, health services research, committee transplantation in the dermatology, committee supportive care and the committee of public relations.
THE 35 LEADING MELANOMA STUDY CENTERS WITHIN THE DECOG

- Kiel
- Tübingen
- Hornburg/Saar
- Mannheim
- Erfurt
- Berlin Charité
- Regensburg
- (Zürich)
- Frankfurt/M.
- Hannover
- Heidelberg
- Minden
- Magdeburg
- Hamburg UKE
- Dresden Uniklinik
- Würzburg
- Buxtehude
- Jena
- München LMU
- Münster
- Erlangen
- Lübeck
- Wuppertal
- Hildesheim
- Bochum
- Köln
- Berlin Neukölln
- Freiburg
- Essen
- Oldenburg
- München TU
- Mainz
- Berlin Prenzlauer Berg
- Dresden Friedrichstadt
- Augsburg
The present executive committee of DeCOG was elected on 29th September 2006, by the general assembly at the 2006 Annual Meeting in Bochum, Germany. The executive committee is elected for 2 years. The next election will be at the DeCOG Annual Conference in September 2008.

**President:** Axel Hauschild, MD
**Vice President:** Dirk Schadendorf, MD
**General Secretary:** Matthias Volkenandt, MD
**Treasurer:** Peter Mohr, MD

**Board of Directors:**
Jürgen Becker, MD PhD
Cornelia Mauch, MD PhD
Uwe Reinhold, MD
Jens Ulrich, MD

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Awards Received by DeCOG Members

The DeCOG members are active in clinical and scientific fields. Members of the DeCOG regularly receive renowned prizes and awards. We would like to mention only a few:

**German Cancer Award**
www.krebsgesellschaft.de/wub_krebspreis,936.html

- **1995:** Claus Garbe, Tübingen
- **2003:** Reinhard Dummer, Zürich
- **2004:** Jürgen Becker, Würzburg
- **2006:** Gerold Schuler, Erlangen
- **2008:** Peter Friedl, Würzburg

**German Skin Cancer Award**
of the German Skin Cancer Foundation
www.hautkrebsstiftung.de/start.html

- **2001:** Uwe Reinhold, Homburg; Jürgen Becker, Würzburg
- **2002:** Hans Starz, Augsburg
- **2003:** Beatrice Schuler-Thurner, Erlangen; Axel Hauschild, Kiel
- **2004:** Peter Friedl, Würzburg
- **2006:** Mirjana Urosevic, Zürich; Margarete und Michael Schön, Würzburg
- **2007:** Anja Bossenhoff, Regensburg
The Dermatologic Cooperative Oncology Group (DeCOG) initiated a huge clinical trial program for melanoma, cutaneous lymphomas, epithelial skin cancer and dermatofibrosarcoma protuberans almost 14 years ago. The network of the society allows us to recruit sufficient numbers of patients for all skin cancers. For example, we are currently enrolling 25 patients per months into adjuvant melanoma and 20 patients per months into stage IV melanoma trials. Typically, DeCOG trials are investigator-initiated trials (IITs) in close collaboration with pharmaceutical companies. Collaboration with other cooperative groups for skin cancer is frequent and always an advantage from our perspective. Apart from clinical trial endpoints, we are interested in translational research projects, typically attached to clinical trials. We have a broad platform of DeCOG centers with an expertise in basic and translational research. Correlating biomarker studies and monitoring evaluation during clinical trials using a huge variety of different research techniques are available. We strongly believe that clinical trials should include translational studies to increase the likelihood of success in the future! A Germany-wide DeCOG biobanking initiative for melanoma is approaching rapidly. The German Melanoma Registry for epidemiological and clinical observation is internationally well known. Along with our research activities, we have developed evidence-based guidelines for the care of patients with a variety of skin tumors. The DeCOG represents the German Cancer Society as well as the German Dermatologic Society in a multidisciplinary setting. S2 guidelines have been published and there is a grant application for S3 guidelines for melanoma and epithelial skin cancer. Furthermore, the DeCOG is the leading society for education in the dermato-oncology area in Germany. We collaborate with sister societies and colleagues in Austria and Switzerland and furthermore with the European Association of Dermato-Oncology (EADO). Our educational campaigns have led to a large number of educational sessions including teaching sessions on how to perform clinical trials that conform to Good Clinical Practice (GCP). We are represented at almost all interdisciplinary oncology meetings in Germany and internationally in educational programs by our opinion leaders.
DeCOG: WHAT CAN WE OFFER?

• an active and relatively young dynamic society for collaboration
• an excellent infrastructure of skin cancer centers with high expertise (an initiative for “Certified Interdisciplinary Skin Cancer Centers”)
• global contacts with almost all collaborative groups and major skin cancer / melanoma centers
• planning and implementation of phase I-IV trials for all types of skin tumors (melanoma, cutaneous lymphoma, epithelial skin cancer, rare neoplasias)
• development of investigator-initiated trials including statistics, biometry and CRF development which conform to GCP
• rapid enrollment of skin cancer patients into clinical trials
• advice in the product development and discussion with regulatory agencies in Germany and Europe
• development of evidence-based guidelines for skin malignancies
• broad basic and translational research expertise in major DeCOG centers (including initiatives for a centralized biobanking systems)
• broad experience in publishing basic, translational and clinical research

Ask us about our expertise in other areas!

BASIC, TRANSLATIONAL AND CLINICAL RESEARCH

The prerequisite for any rational, evidence-based and ultimately successful therapy is an understanding of the underlying disease. The DeCOG has created a network which brought together basic, translational and clinical research groups now tackling carcinogenesis and particularly melanogenesis. Early stages of melanoma are successfully treated with surgery in the majority of cases, but advanced disease is generally refractory to conventional chemotherapy. There is therefore much interest in the field in novel therapeutics, specifically immunotherapy and targeted therapies. Our understanding of this complex and often unpredictable disease is expanding based on new developments in immunology and tumor genetics. While basic knowledge may be generated by use of in vitro and preclinical in vivo systems, such results need to be validated in human disease. To ensure this translational research, the DeCOG established an internet-based databank together with a linked decentralized biobank including tumor tissue, tumor and somatic DNA, serum, and peripheral blood. Most notably, this biobank was largely derived from patients treated within clinical trials making it possible to establish the predictive value of biomarkers for treatment outcome. New therapeutic approaches, besides monoclonal antibodies and vaccination, include an increasing number of small molecules that have been shown to interfere restrictively with intracellular signaling pathways in melanoma and decrease proliferation, survival, migration or invasion. Other agents can interfere with stromal components of melanoma, such as angiogenesis and components of the immune system.

This large variety of possible treatment options calls on one hand for controlled clinical trials combined with basic and translational research to establish new instruments and algorithms’ for a stratified or even individualized medicine.
GUIDELINES FOR MANAGEMENT OF SKIN TUMORS

Guidelines have been developed in an interdisciplinary fashion under the auspices of the German Cancer Society and the DeCOG since 1996. These guidelines have been written in order to help clinicians diagnose, treat, and follow skin cancer patients. They help caregivers improve the management of skin cancer patients. The guidelines are also intended to promote the integration of care between medical and paramedical specialties for the benefit of the patient.

These guidelines have been established by interdisciplinary expert groups which analyze all relevant international literature; they are then approved by the relevant medical professional associations. They take into consideration the present standard of knowledge and describe “state of the art” diagnostic and therapeutic approaches. Approval has been obtained from the different scientific specialty groups, coordinated by the Information Center for Standards in Oncology (ISTO, German Cancer Society). Eight different working parties of the German Cancer Society took part in this process. The Association of the Scientific Medical Societies in Germany organized the process of approval with 11 different scientific medical societies. Claus Garbe, MD, Tübingen, coordinated the activities of the various groups, the selected experts, and the final authors. Guidelines were established for the following tumors and have been published in a long version and as brief guidelines:

- Malignant melanoma of the skin
- Basal cell carcinoma
- Squamous cell carcinoma
- Merkel cell carcinoma
- Dermatofibrosarcoma protuberans
- Kaposi sarcoma
- Cutaneous lymphomas
- Melanocytic nevi
- Actinic keratosis

The current Germany melanoma guidelines are published in Melanoma Research:


*Melanoma Res.* 2008 Feb;18(1):61-7

*Melanoma Res.* 2007 Dec;17(6):393-9

EDUCATIONAL ACTIVITIES

In order to improve the quality of care of patients with skin cancer the Dermatologic Cooperative Oncology Group (DeCOG) has initiated a broad educational program, which is offered to dermato-oncologists around the country.

Various programs covering the standard as well as experimental treatment of malignant melanoma, epithelial skin tumors, cutaneous lymphomas and Merkel cell carcinoma have been developed and are regularly offered:

- A half-day educational symposium of practical dermato-oncology is provided quarterly in various cities of Germany for all dermato-oncologists of the region.
- As part of the annual meeting of the German Cancer Society (Deutsche Krebsgesellschaft), a half-day interdisciplinary educational symposium is offered. A similar symposium is offered as part of the biannual meeting of the German Dermatological Society (“Deutsche Dermatologische Gesellschaft”).
- Several courses teaching how to perform clinical studies conforming to GCP-standards have been offered.
- Annually since 2006, a 40-hour course systematically covering all aspects of medical therapy of malignant skin tumors is offered. Approximately 80 – 100 dermato-oncologists attend. Those who pass the written exam achieve a certificate valid for 5 years.
- Members of the board of the DeCOG are frequent speakers at educational activities initiated by other cancer societies.
INTERDISCIPLINARY MELANOMA CENTERS AND THEIR CERTIFICATION

Steps to the Certified Skin Cancer Center

Skin Cancer Center (SCC)  OnkoZert Certification Institute of the German Cancer Society (GCS)  Certification Commission GCS approved experts  Board of Certification GCS approved experts  KTQ/ISO 9001 Certifying Institutes

Requirements of SCC
- Elaboration of SC questionnaire
- Identification of deficits compared to requirements for SCC

Start of SCC Certification
- Application for SCC Certification
- Selection of experts
- Planning of certification audit
- Check of questionnaire
- Approval for certification process

Introduction QA-System
- Selection of QA-Model (ISO 9001 or KTQ)
- Establishment of QA system
- Selection of QA certifying institute

Certification audit
- Introduction of changes according to requirements
- Review by Board of Certification
- Certification QA system
- Certification by GCS

Certification of Skin Tumor Centers

Dermato-Surgery
- tumor excisions
- micrographic surgery
- plastic & reconstructive surgery
- SLNB

Medical Therapy
- chemotherapy
- immune therapy
- targeted therapy
- vaccination

Experimental Research
- molecular biology
- cell culture
- animal testing
- immunology

Clinical Research
- clinical studies
- epidemiology
- blood and tissue bank

Patient Follow up
- structured examination
- radiological examinations
- tumormarker
- documentation

Development of interdisciplinary guidelines
## LIST OF CLINICAL TRIALS

### 1. TRIALS CLOSED FOR RECRUITMENT:

#### 1.1 ADJUVANT TRIALS in MELANOMA STAGE II/III

**Short title:** DeCOG-MM-ADJ-0 (PI: G. Burg, MD and R. Dummer, MD)

**Title:** Prospective randomized trial of interferon alpha-2b and interleukin-2 as adjuvant treatment for resected intermediate- and high-risk primary melanoma without clinically detectable node metastasis

**End of recruiting:** 1995

**No of patients:** 225

**Publications:**

**Short title:** DeCOG-MM-ADJ-1 (PI: C. Garbe, MD)

**Title:** Randomized multicenter study protocol on the efficacy of an adjuvant treatment with INF-2-alpha (Roferon-A) or a combination of IFN-2-alpha and DTIC versus studying melanoma patients with lymph node metastases (stage IIIB)

**End of recruiting:** 2001

**No of patients:** 444


**Short title:** DeCOG-MM-ADJ-2 (PI: A. Hauschild, MD)

**Title:** Randomized multicenter study on the efficacy of different interferon-a-2b doses (Intron-A) in the adjuvant therapy of melanoma patients with high-risk primary tumors (tumor thickness > 1.5 mm; DDG-stage IIA+B)

**End of recruiting:** 2001

**No of patients:** 674

**Publication:** (manuscript in preparation).

**Short title:** DeCOG-MM-ADJ-3 (PI: C. Garbe, MD)

**Title:** Prospective-randomized study on the efficacy of an adjuvant therapy of the metastatic melanoma with vindesin versus studying patients after an operative resection of metastases (stage IIIA, IIIB-relapse, IV)

**End of recruiting:** 2001

**No of patients:** 142

**Publication:** (manuscript in preparation)

**Short title:** DeCOG-MM-ADJ-4 (PI: A. Hauschild, MD)

**Title:** Randomized multicenter study on the efficacy of interferon-alpha-2a doses (Roferon-A) in the adjuvant therapy of melanoma patients with high-risk primary tumors (tumor thickness > 1.5 mm; DDG-stage IIA+B) for a period of 18 vs. 60 months

**End of recruiting:** 2004

**No of patients:** 880

**Side study QoL:** Title: Neurotoxicity adverse events

**Publication:** (manuscript to be prepared in 2008)

**Short title:** DeCOG-MM-ADJ-6 (PI: C. Garbe, MD) in co-operation with EADO

**Title:** Randomized, multicenter phase III trial comparing adjuvant treatment with PegIntron over 36 months versus reference treatment with IntronA over 18 months in cutaneous melanoma patients AJCC Stage II (>1.5 mm, clinically node negative)

**End of recruiting:** 2005

**No of patients:** 890

**Short title:** DeCOG-MM-ADJ-9 (PI: C. Garbe, MD)

**Title:** Randomized, multicenter, open label study to compare the efficacy and tolerability of pegylated interferon-alpha-2a (PEG-IFN) to “low dose” interferon-alpha-2a in patients with malignant melanoma in stages IIA (T3a) – IIIB (AJCC-2002)

**End of recruiting:** 2007

**No of patients:** 880
1.2 TRIALS in MELANOMA STAGE IV
(closed & published)

**Short title:** DeCOG-MM-PAL-1 (PI: W. Tilgen, MD)
**Title:** Randomized, multicenter study on the efficacy of a combined treatment with DTIC and IFN-a versus a combination of DTIC, IFN-a and IL-2 on malignant melanoma patients in the stage of distant metastasis (stage IV)
**End of recruiting:** 1998
**No of patients:** 290

**Short title:** DeCOG-MM-PAL-2
(PI: R. Kaufmann, MD)
**Title:** Randomized, multicenter study on the efficacy of a combined treatment with temozolomide and interferon alpha versus temozolomide alone on malignant melanoma patients in the stage of distant metastasis (stage IV)
**End of recruiting:** 2001
**No of patients:** 294

**Short title:** DeCOG-MM-PAL-2A
(PI: R. Kaufmann, MD)
**Title:** Randomized, multicenter study on the efficacy of a first-line treatment of the combined treatment with temozolomide and pegylated interferon alpha versus temozolomide alone on stage IV melanoma patients
**End of recruiting:** 2004
**No of patients:** 125

**Short title:** DeCOG-MM-PAL-3
(PI: D. Schadendorf, MD)
**Title:** Second-line therapy with weekly paclitaxel and carboplatin versus paclitaxel alone in melanoma patients with distant metastases (stage IV)
**End of recruiting:** 3/2000
**No of patients:** 40

**Short title:** DeCOG-MM-PAL-4
(PI: D. Schadendorf, MD)
**Title:** Randomized, multicenter study on the efficacy of dacarbazine (DTIC) versus vaccination with autologous peptide-pulsed dendritic cells (DC) in first-line treatment of patients with metastatic melanoma: a randomized phase III trial (stage IV)
**End of recruiting:** 3/2003
**No of patients:** 108

**Short title:** DeCOG-MM-PAL-5
(PI: D. Schadendorf, MD)
**Title:** Clinical phase II study on the efficacy of a treatment with temozolomide with different doses in patients with asymptomatic brain metastases from malignant melanoma in the stage of distant metastases (stage IV)
**End of recruiting:** 4/2004
**No of patients:** 45

**Short title:** DeCOG-MM-PAL-6 (PI: U. Reinhold, MD)
**Title:** Multi-center phase-II study for a first-line selective chemotherapy after pre-therapeutic sensitivity-directed chemotherapy in metastatic melanoma patients
**End of recruiting:** 04/2004
**No of patients:** 82
**Publication:** S Ugurel, D Schadendorf, C Pföhler,
2. STUDIES WITH ONGOING RECRUITMENT (MAY 2008)

2.1 Adjuvant Melanoma Trials

Short title: DeCOG-MM-ADJ-5 (PI: P. Mohr, MD)

Title: Randomized multicentre study for adjuvant treatment of stage III (AJCC 2002) malignant melanoma: intermittent high-dose i.v. interferon alpha-2b versus standard high-dose interferon alpha-2b therapy

Site study: Quality of life depression and fatigue of patients treated with high-dose interferon alpha-2b within the DeCOG study (DeCOG MM-ADJ-06) (P. Mohr, MD, M. Weichenthal, MD)

No of patients: 550/600 patients in 04/2008
Expected study end: Q IV/2008

2.2 Melanoma Stage IV

Short title: DeCOG-MM-PAL-9 (PI: A. Hauschild, MD)

Title: Combined treatment of sorafenib and pegylated interferon 2b in stage IV metastatic melanoma: a prospective non-randomized, multicenter Phase II Study

No of patients: 9/55 in 04/2008
Start of study: March/2008

2.3 Cutaneous Lymphoma

Short title: ADO-CTCL-3 (TARADO) (PI: R. Dummer, MD)

Title: Multicenter therapy protocol for bexarotene (Targetin®) monotherapy for previously treated CTCL stage >Ib with unequivocal EORTC diagnosis

No of patients: 95/200
End of recruitment: 2010
REGISTRIES AND NETWORKS

MERKEL CELL CARCINOMA REGISTRY
Purpose of Registry
This is a centralized German registry for Merkel cell carcinoma. It is patterned after the successful central melanoma registry. Data of the affected patients as well as tumor data are collected. Registration is done voluntarily after obtained informed consent. A scientific analysis of the data will be done at regular intervals.

Organization
Project leader: Jürgen C. Becker, MD PhD
Office: Brigitte Bauer
Address:
Klinik und Poliklinik für Dermatologie, Venerologie und Allergologie
Universitätsklinikum Würzburg
Josef-Schneider-Straße 2, 97080 Würzburg
Website: www.ado-homepage.de
Email: merkel@ado-homepage.de

NEVUS NETWORK INCLUDING REGISTRY
The DeCOG supports the efforts of the Nevus-Network, a non-profit organization founded by German dermatologists offering a patient oriented web service and registry for patients with large congenital nevi and neurocutaneous melanocytosis.

Organization
Project leader: Sven Krengel, MD
Address:
Nävus-Netzwerk
S. Krengel MD
Moislinger Allee 95, 23558 Lübeck
Tel.: +49 (0) 0451/81551
www.naevus-netzwerk.de
Registration Form:
The registration form can be downloaded from the homepage of the network.

CENTRAL CUTANEOUS LYMPHOMA REGISTRY
The Central Cutaneous Lymphoma Registry of the German Dermatologic Society was established in 1998 as a clinic-based cancer registry. To date, 26 clinics from all German states, have participated. After obtaining informed consent, patients complete clinical information, including TNM stage, histology and molecular biological data as well treatment modalities are documented. Recently the first evaluation of the German Central Registry for Cutaneous Lymphomas of the German Society of Dermatology was published.

Organization
Project leader: Chalid Assaf, MD
Address:
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Skin Cancer Center Charité
Charitéplatz 1, 10117 Berlin
Tel.: +49 (0) 030-450518213
Tel.: +49 (0) 030-84456910
Website: www.charite.de/ch/derm
E-mail: chalid.assaf@charite.de
Committees

Committee Clinical Studies
This group coordinates the clinical studies of DeCOG dealing with the many different types of skin cancers.
- Uwe Trefzer, MD (chair)
  E-mail: uwe.trefzer@charite.de

Committee on Advanced training
This committee coordinates advanced training courses in dermato-oncology for DeCOG members.
- Matthias Volkenandt, MD (chair)
  E-mail: matthias.volkenandt@med.uni-muenchen.de

Committee on Public Relations
This committee is charged with presenting the interests of DeCOG to the publics. Methods include:
1. Homepage: www.ADO-Homepage.de
2. News letters for members
3. Training sessions for public relations activities
- Peter Mohr, MD (chair)
  E-mail: peter.mohr@elbekliniken.de
- Thomas Eigentler, MD (web site master)
  E-mail: thomas.eigentler@uni-tuebingen.de

Committee on Guideline-Development
This group regularly revises the DeCOG guidelines on diagnosis, therapy and follow-up for all the major types of skin cancer.
- Claus Garbe, MD (chair)
  E-mail: claus.garbe@med.uni-tuebingen.de

Committee on Translational Research/Biobank
This committee is charged with facilitating the implementation of advances in the understanding of skin cancer into the clinical situation; thereby improving the clinical care of the patient.
- Schadendorf, MD (chair)
  E-mail: d.schadendorf@dkfz.de

Committee of Quality Assurance
This committee directs the implementation of quality standards in all areas relevant for skin cancer patient care in order to allow access to up-to-date diagnostics and treatment regimens for our patients and to allow detailed analysis of clinical practice in our centers.
- Schadendorf, MD (chair)
  E-mail: d.schadendorf@dkfz.de

Committee on Outpatient Dermato-Oncology
This committee attempts to optimize the interaction between hospital-based and outpatient, primarily private practice dermato-oncology units. Activities include
1. Surveys to investigate the current health care provision for skin cancer patients
2. Development of clinical pathways that more efficiently link treatment and aftercare between inpatient and outpatient settings
3. Implementing comprehensive quality management measures to increase adherence to dermato-oncologic guidelines
- Uwe Reinhold, MD (chair)
  E-mail: u.reinhold@medizinisches-zentrum-bonn.de

Committee on Skin Tumors in Organ transplanted patients
About 4000 organ transplantations are performed annually in GERMANY: The patients are then treated for the rest of their life with immunosuppressive regimens which facilitate the development of epithelial skin tumors. On average the first tumors appear 3-5 years after transplantation and are one of the major causes of mortality after transplantation. This committee is charged with exploring the causes, prevention and care of these secondary epithelial tumors. It is part if the European network SCOPE.
- Eggert Stockfleth, MD (chair)
  E-mail: eggert.stockfleth@charite.de

Committee on Health Services Research
This committee concerns itself through a variety of projects with the availability of comprehensive care for dermato-oncology patients, monitors confirmation with guidelines and screening recommendations and serves as an important link between hospital-based and outpatient community-based care of skin cancers.
- Matthias Augustin, MD (chair)
  E-mail: m.augustin@uke.uni-hamburg.de

Committee on Supportive Care
This committee is concerned with questions and research about palliative care in dermato-oncology, and supports with projects and educational efforts optimal supportive care for dermato-oncology patients.
- Carmen Loquai, MD (chair)
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