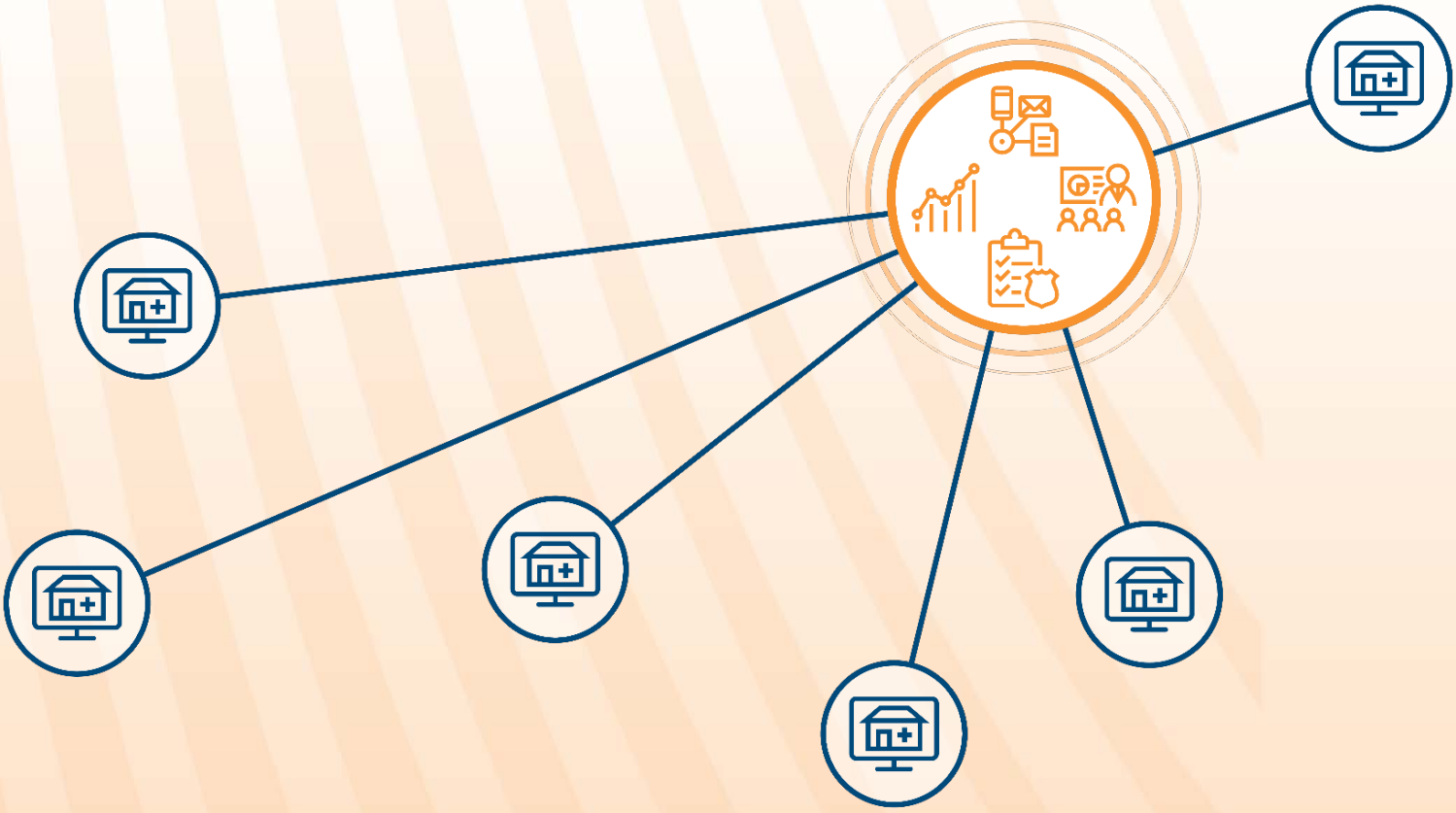
Arbeitsgemeinschaft
Dermatologische Onkologie
ADO

ADOREG

Bundesweites prospektives Register zur Versorgungsforschung in der dermatologischen Onkologie

[Nationwide German prospective registry for health services research in dermatologic oncology]



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1. Introduction

The Arbeitsgemeinschaft Dermatologische Onkologie [German Working Group on Dermatological Oncology (ADO)] is the working group of the Deutsche Krebsgesellschaft [German Cancer Society (DKG)] and the Deutsche Dermatologische Gesellschaft [German Dermatological Society (DDG)]. As a responsible scientific association, the ADO is committed, among other things, to promoting clinical and experimental research in this academic field, establishing guidelines for dermatologic oncology, and improving and monitoring the quality of dermato-oncological patient care. IQVIA is a clinical research organization (CRO) that already has many years of experience in developing and operating cancer registries.

The skin cancer registry ADOReg was developed by ADO and ONKODATAMED GmbH working in collaboration. ONKODATAMED GmbH was acquired by IQVIA in May 2018.

The aim of the ADOReg project is to facilitate oncology health services research, which is gaining an ever-increasing significance for all parties involved in the healthcare system.

On the one hand, the information collected corresponds to tumor-based data documentation according to an epidemiological cancer registration – in order to be able to use this data for the purposes of the participating center. On the other hand, the registry includes treatment and historical data on the documented patients, which should enable realistic health services research that is in line with clinical practice.

In addition, the registry provides a platform that enables specific research projects to be carried out within the framework of the scientific association and its working groups to a defined standard. In this case, all participating centers and participating physicians have the opportunity to develop their own projects and to carry them out on the ADOReg platform. The results will be presented at scientific conferences, among other things, and published in relevant scientific journals.

The registry also has the additional purpose of processing the data for the upcoming purposes of the German clinical cancer registry and for key performance indicators in quality assurance, for example, as part of the certification process for skin cancer centers.

Combining all these purposes on a single platform has the crucial advantage of being able to collect data only once and no longer redundantly for different purposes. The standardization of the data formats and the patients consenting to the extensive scientific use of their data also provides the opportunity to use the data collected for updated projects within the framework of the ADO.

In order to counteract the significant increase in expenses resulting from the scope and depth of documentation required in the clinical cancer registration, ADOReg has created the possibility of providing performance-related compensation to the centers involved in the documentation by means of third party funding. To this end, ADOReg is conducting contract research to raise appropriate funds. The data themselves are strictly confidential and are pseudonymized accordingly. Third parties shall only be provided with analyses and/or reports at an aggregated level, so that they are de facto anonymous.

2. Legal basis

The legal basis of the project is the “Cooperation agreement on the establishment and operation of a prospective registry for health services research in dermato-oncology” between the DKG and IQVIA.

In addition, IQVIA shall conclude an “Agreement on the documentation and submission of the courses of treatment in a prospective online registry for health services research in dermatologic oncology (ADOReg)” with each skin tumor center that wants to contribute to ADOReg. The purpose of this agreement is to bindingly establish the mutual rights and obligations as well as the conditions under which data collection, transfer, analysis, and use shall be carried out. All applicable legal regulations shall be complied with in all contractual agreements and in the technical implementation of the project, with particular emphasis on compliance and data protection regulations.

3. Project committees

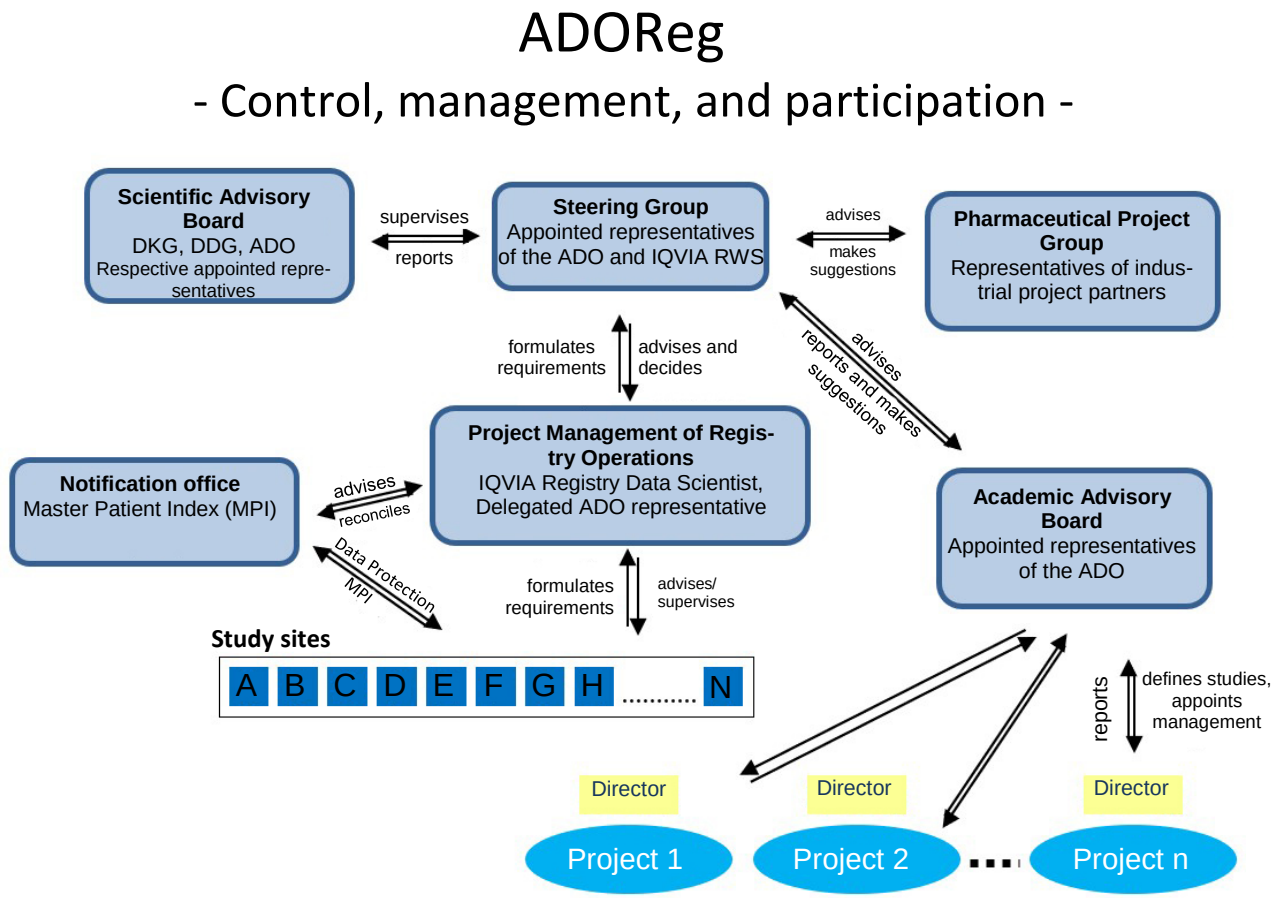

Figure 1 The registry's project committees

ADO = Arbeitsgemeinschaft Dermatologische Onkologie [German Working Group on Dermatological Oncology]
DDG = Deutsche Dermatologische Gesellschaft [German Dermatological Society]
DKG = Deutsche Krebsgesellschaft [German Cancer Society]
IQVIA RWS = IQVIA Real World Solutions

3.1. Scientific Advisory Board

The Scientific Advisory Board is the most senior supervisory body for all medical and scientific processes that affect ADOReg. In particular, it supervises the medical and scientific activities of the Steering Group and reviews their annual report. The Scientific Advisory Board consists of one representative from the DKG, the German Dermatological Society (DDG), and the ADO respectively.

3.2. Steering Group

Decisions on all relevant issues relating to the operation and further development of the registry shall be made by the Steering Group by mutual agreement.

This includes, among other things, questions relating to the nature and scope of the data to be collected and their use, compensation to the participating centers, and the acceptance of commercial (contract research) and non-commercial ("academic" research) projects.

3.3. Pharmaceutical Project Group

The Pharmaceutical Project Group consists of representatives of industrial project partners, but these members may change according to the projects and their duration. The projects may be individual studies or general support for the ADOReg registry. Documentation in the registry is independent of this and is not affected by these projects.

In addition, the codes of the association "Freiwillige Selbstkontrolle für die Arzneimittelindustrie [Voluntary Self-Regulation for the Pharmaceutical Industry]" (FSA e.V.) shall be observed. Three codes have been developed to date: The first code is for professionals, the second is for cooperation with patient organizations, and the third is the transparency code. Herein, the basic rules of conduct are defined and adjusted on a regular basis. Compliance with these rules is independent of membership with the FSA e.V.

3.4. Project Management of Registry Operations

The operation of the registry and the basic software for data collection shall be led by a representative of the ADO and the responsible employee at IQVIA, the designated Registry Data Scientist. The aim and purpose of this group are the maintenance and optimization of the base registry.

3.5. Academic Advisory Board

The Academic Project Advisory Board comprises five members and shall be appointed by the Steering Group in agreement with the Scientific Advisory Board for a term of five years. Reappointment is possible.

The Academic Project Advisory Board is the direct contact for all persons or institutions submitting any type of academic study.

4. Medical/technical project description

ADOReg shall be implemented with the following sub-registries:

- Malignant melanoma
- Basal cell carcinoma
- Merkel cell carcinoma
- Cutaneous squamous cell carcinoma

The online quality assurance and documentation system QuaSi® is the basis for the registry's program software and database. In order to use it (for online data entry), it only needs an internet-enabled PC with (preferably) Mozilla Firefox browser. The central database underlying the system is an Oracle Database.

There is also the opportunity to carry out enriched studies based on the registry. For this type of study, the obligatory data to be collected for the registry is enriched by project-relevant data. This not only reduces the documentation required for study staff, but also enables the study group to be observed to be precisely narrowed down based on the required parameters.

5. Data protection concept

One of the primary objectives of the registry is to monitor patients over a long period of time. In other words, multiple data on different times, different treatment contexts (e.g., treatment cycles, aftercare, or sequelae), and, most likely, different treating institutions (e.g., outpatient, inpatient, change of physician) shall be recorded for a patient.

These requirements and the need for longitudinal and inter-institutional analyses form the basis for which data protection measures must be met. In order to ensure compliance with data protection regulations within the framework of the ADOReg project, several complementary, technical, contractual, and organizational measures shall be taken.

The key element of data protection is the Master Patient Index (MPI). This allows for the strict separation of the personal data from the medical data and a secure pseudonymization of the medical data.

To generate the MPI, ADOReg uses the Mainzelliste process. A patient pseudonym is generated by the well-established algorithm of the Mainzelliste.

This ensures that a uniform pseudonym can be used across all centers, while the medical data cannot be traced back to the patients themselves.

The security of the pseudonym is guaranteed by the fact that it is generated by an independent third party. The independence of this third party is the result of the technical and organizational separation of ADOReg and the underlying agreements (in particular with regard to absolute independence).

From a technical point of view, the separation of data entry, pseudonymization, and data storage is crucial for data protection.

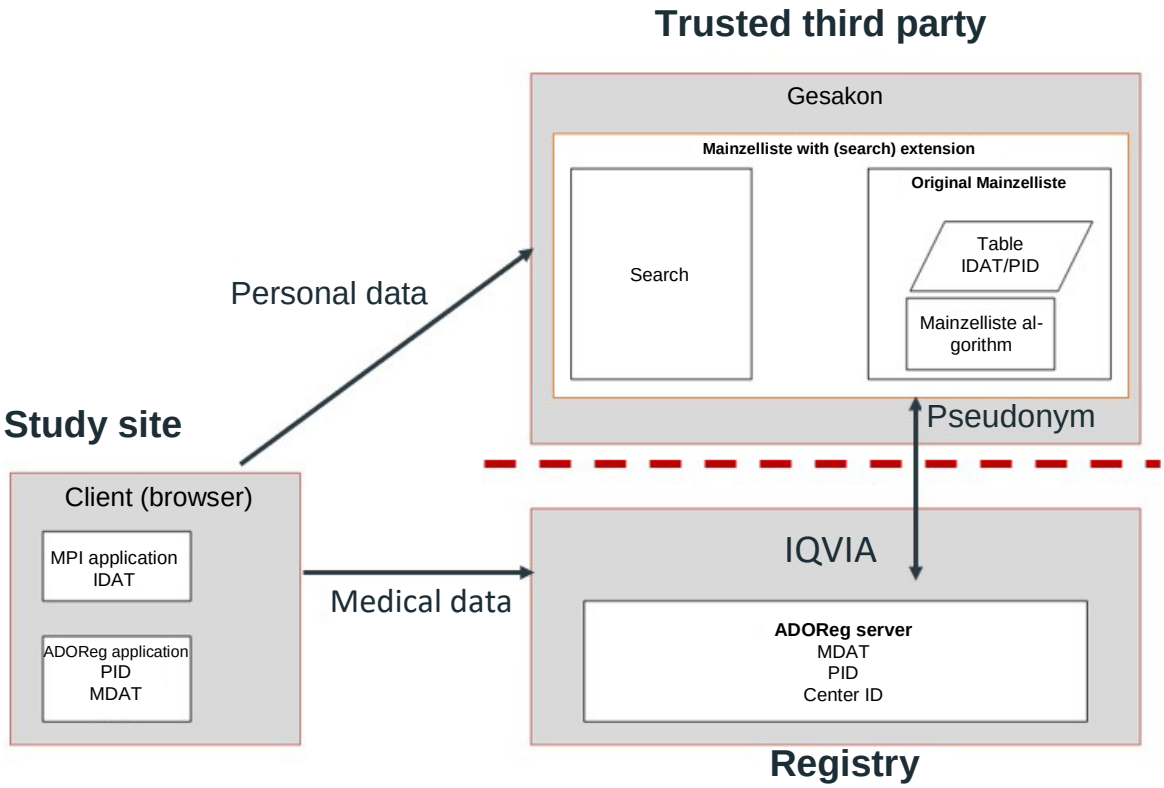

Figure 2 Graphic presentation of the separation of data entry, pseudonymization, and data storage
Center = data entry
Trusted third party = pseudonymization
Registry = pseudonymized data storage

The storage of the medical data (IQVIA) is strictly separated from the MPI service (Gesakon) and the centers which hold the personal data. Communication between these systems is carried out via secure connections using state-of-the-art technology.

The authorizations are controlled via authentication at ADOReg and are obtained by tokens between the systems.

The data flow between the systems is limited to what is strictly necessary.

Another fundamental data protection measure is physical access protection to the data stores at the current level of security.

6. Data quality

Ensuring a high standard of data quality is essential for the scientific success of ADOReg. This shall be achieved through numerous technical and organizational measures, which are summarized in the following figure:

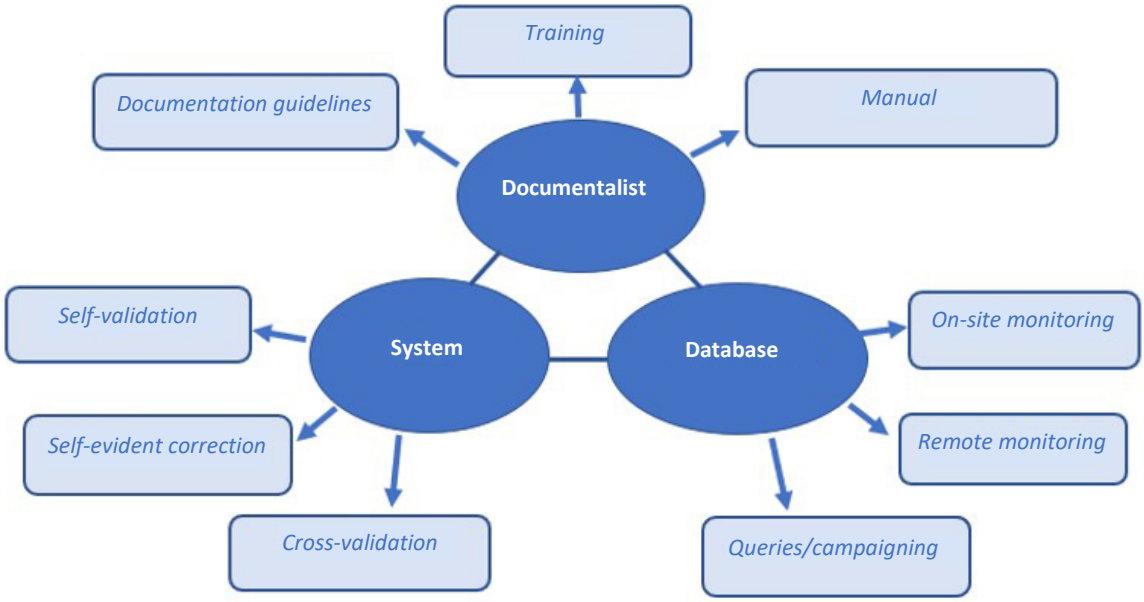

Figure 3 Technical and organizational measures for quality assurance

On the system side, the electronic Case Report Form (eCRF), QuaSi® DERMA, shall carry out reviews of the data entered by the documentalist wherever it is medically reasonable and technically feasible, e.g., whether these data are within the predefined range (self-validation) or whether they are inconsistent with data entered elsewhere (cross-validation).

The database shall be regularly checked by its own monitors in order to detect any contradictions that are not automatically identifiable by the system. These shall also be clarified with the documentalists either by phone or in on-site campaigns.

The documentalists themselves are obliged to carry out the documentation according to the “Principles of Documentation” of the ADO (see Appendix 1). They are also supported by regular training sessions and by IQVIA’s own hotline.

6.1. Ethics Committee vote

Before the start of ADOReg operations, an assessment for the project from the Ethics Committee of the Universitätsklinik Duisburg-Essen [University Hospital Duisburg-Essen] was obtained and approval was issued.

6.2. Patient Information and Informed Consent

The pseudonymized treatment data of a patient shall only be documented in the ADOReg registry if the patient was previously informed by the treating physician about the purpose of the registry and the data protection measures, and if the patient has consented to the storage and scientific analysis of their pseudonymized data.

6.3. ADOReg newsletter

Newsletters shall be published several times a year for ADOReg users.

7. Contact person

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Appendix 1: Principles of Documentation

1. The documentation shall be carried out uniformly and electronically, with software support, based on the resolutions and practices agreed between the ADO and IQVIA.

2. The documentation must be carried out carefully, objectively, completely, and medically rationally.

3. It must correspond to the truth and be carried out promptly.

4. An incomplete or illogical dataset shall not be included in the analysis.

5. The Project Management shall decide on the scope, content, and completeness of the documentation on a case-by-case basis.

6. In the event of repeated, incomplete, or implausible documentation, the center must explain itself in front of the Steering Group.

7. The documentation must not have any influence on treatment decisions, procurement transactions, etc., in medical and clinical activities.

8. Patients and/or healthcare payers or other third parties, in particular statutory health insurance (GKV) providers and/or private health insurance (PKV) providers shall not bear any costs for the documentation, including direct or indirect additional or ancillary costs.

9. The documentation must be carried out in strict compliance with the statutory regulations and rules of ethics, in particular the Datenschutzgesetz [German Data Protection Act].

10. Every person that undertakes documentation shall be held liable for compliance with these documentation guidelines.