

HIVCAre Documentation

**Epidemiology and Inpatient Care Characteristics of HIV-positive Cancer Patients
in German university hospitals**

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1 About This Documentation

This Research Documentation means to provide both a comprehensive source of information about the underlying project as well as facilitate its cooperative approach. Following the general ideas of [Open Science](#), we thus hope to achieve a high degree of transparency and reproducibility in our conduct of research.

The design of this Documentation follows the guides on [Good Epidemiological Practice \(GEP\)](#)¹ and [Gute Praxis Sekundärdatenanalyse \(GPS\)](#)².

1.1 Guiding Principles

[Open Science Principles](#)

[Good Epidemiological Practice \(GPE\)](#)

[Gute Praxis Sekundärdatenanalyse \(GPS\)](#)

[FAIR Principles](#)³

[STROBE Statement](#)

Part I

Project Information

2 Project Synopsis

2.1 Project Background

- Infection with Human Immunodeficiency Virus (HIV) and its consequential acquired immune deficiency syndrome (AIDS) entail an increased risk of developing cancer. The associated malignancies are commonly classified into AIDS-defining cancer (AD, e.g. Kaposi sarcoma) and HIV-associated non-AIDS-defining cancer (NAD, e.g. Hodgkin lymphoma).
- Establishment of effective antiretroviral therapy (ART) is considered a major driver of the steep decline in AD cancer incidence since the 1990s, however the risk of NAD cancer in persons living with HIV (PLWH) remains elevated compared to non-infected individuals. Today cancer is the leading cause of death among the infected population, a fact that has in part been attributed to the considerable rise in life expectancy.
- Medical care of HIV-positive cancer patients involves management of complex interactions between ART and potential side effects, anti-infective therapy as well as cancer treatment in a latently immunocompromised host.
- Currently no specific care structures have been established in German hospitals to meet this medical challenge.
- Exploration of Real World Data could provide insights into epidemiology and inpatient care characteristics of HIV-positive cancer patients.
- We analyze data curated in the context of a federal law (Krankenhausentgeltgesetz, KHEntgG), that requires all German hospitals to transmit the so-called §21-data-set to a semi-public institute (InEK GmbH) under management of central health system organization.
- The correspondent data base is curated and hosted by hospital infrastructure and can be accessed by Data Integration Centers.
- Using federated analysis techniques ensures a high level of data privacy and maintains data sovereignty of the participating sites.

3 Project Governance

3.1 Full Project Title

Epidemiology and Inpatient Care Characteristics of HIV-positive Cancer Patients in German university hospitals: A Real World Data Exploration (HIVCAre).

3.2 Project Initiation

Prof. Dr. Jörg Janne Vehreschild
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3.3 Project Supervision

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3.4 Project Administration

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3.5 Research Associates

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Stephan	Christoph	HIVCENTER, Medical HIV Treatment and Research Unit, Johann Wolfgang Goethe
Vehreschild	Jörg Janne	Department of Medicine, Hematology and Medical Oncology, University Hospital
Wehrle	Julius	Data Integration Center, University Hospital Freiburg, Freiburg

3.6 Participating Institutions

City	Hospital	University	Institution
Cologne	Uniklinik Köln	Universität zu Köln	Medical Data Integration
Frankfurt/Main	Universitätsklinikum Frankfurt	Goethe-Universität Frankfurt	Datenintegrationszentrum
Freiburg	Universitätsklinikum Freiburg	Albert-Ludwigs-Universität Freiburg	Datenintegrationszentrum
Munich	LMU Klinikum	Ludwig-Maximilians-Universität	Zentrum für Medizinische

3.7 Funding

There is no third-party funding for this project.

3.8 Conflicts of Interest

We have no conflicts of interest to disclose.

3.9 Publication

The study results will be published in cooperation with all associates.

4 Study Design

HIVCAre is a multicenter retrospective cohort study, conducted on Real World Health Data from German university hospitals.

4.1 Research Objectives

Main Objective: Explore epidemiology and inpatient care characteristics of HIV-positive cancer patients

- Describe cancer occurrence in HIV-positive patients over time stratified by cancer category
- Explore possible differences in care characteristics between HIV-negative and HIV-positive cancer patients
- Explore differences in course of therapy between HIV-negative and HIV-positive cancer patients

For a detailed list of Research Items, see according Section [below](#).

4.2 Study Data

The primary health data analyzed in this study is curated by hospitals following legal requirements founded in [§21 Krankenhausentgeltgesetz \(KHEntgG\)](#). For more details, see Chapter [Study Data](#).

4.3 Study Cohort

Data of patients admitted to the following university hospitals (in alphabetical order):

City	Hospital	University
Cologne	Uniklinik Köln	Universität zu Köln
Frankfurt/Main	Universitätsklinikum Frankfurt	Goethe-Universität Frankfurt

4.3.0.1 Inclusion criteria

- Admitted between 01-01-2005 and 12-31-2019
- Aged at least 18 years at date of admission
- At least one documented ICD-10 code representing malignancy or HIV infection

4.3.0.2 Exclusion criteria

- Implausible documentation of ICD-10 codes

4.3.1 Stratification Model

4.4 Sample Size Determination

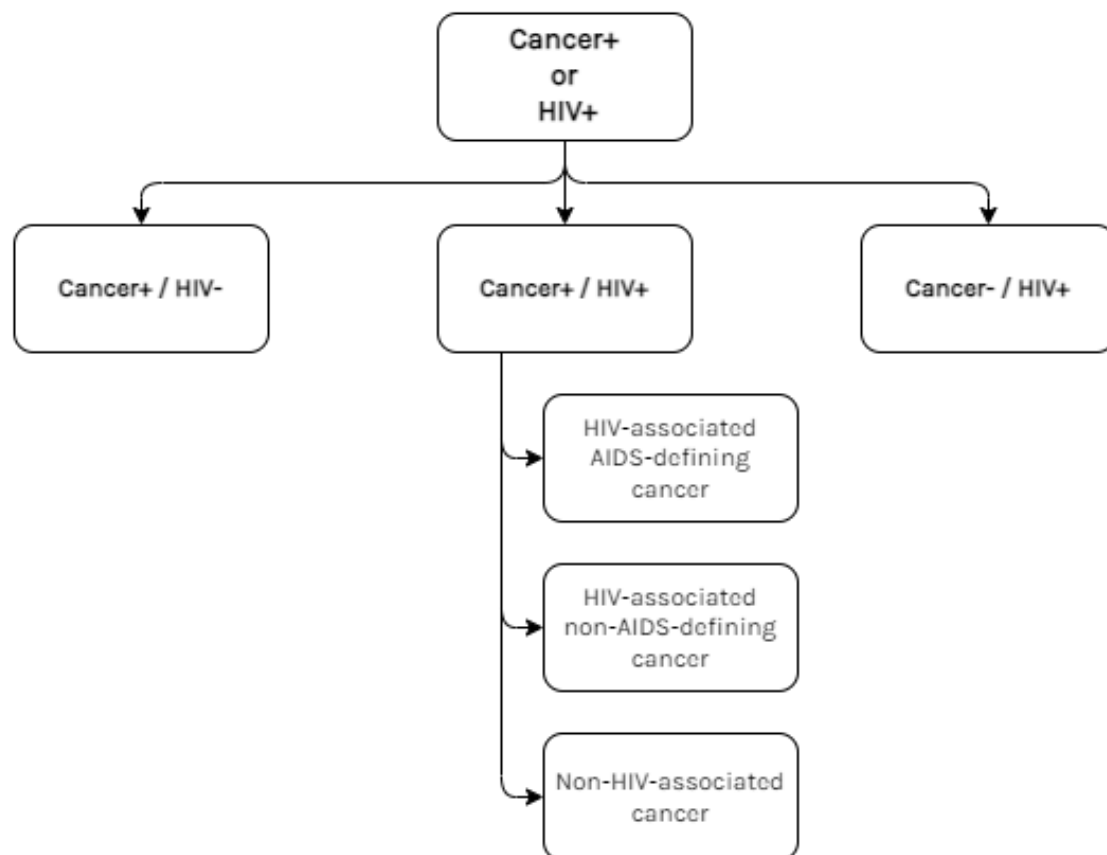
Since this study does not aim at a particular effect size analysis and it can be assumed that the yielded Sample Sizes will be rather large, no specific Sample Size Determination will be performed.

4.5 Research Items

The following research items result from the research objectives stated [here](#).

Item	Compared Strata	Research Item
Epidemiology		
1	All main subgroups	Sample size over time
2	All main subgroups	Age distribution over time
3	All main subgroups	Gender distribution over time
4	All main subgroups	Spatial distribution
7	Cancer+/HIV+	Occurrence of different HIV-associated cancer diagnoses over time
8	Cancer+/HIV-	Occurrence of different HIV-associated cancer diagnoses over time
9	Cancer+/HIV+	Projection of HIV-associated cancer diagnoses
10	Cancer+/HIV+	Occurrence of AIDS in cancer patients, stratified by cancer category

11	Cancer+/HIV+	Occurrence of AIDS code after chemotherapy
12	Cancer+/HIV+	Presumed order of diagnosis of HIV infection and cancer over time
13	Cancer+/HIV- vs. Cancer+/HIV+	Age at presumed cancer onset
14	Cancer+/HIV- vs. Cancer+/HIV+	Cancer topography grouped by organ
15	Cancer+/HIV- vs. Cancer+/HIV+	Cancer topography grouped by organ over time
16	Cancer+/HIV- vs. Cancer+/HIV+	Projection of cancer topography grouped by organ
17	Cancer+/HIV- vs. Cancer+/HIV+	Cancer topography grouped by ICD-10 grouping
18	Cancer+/HIV- vs. Cancer+/HIV+	Cancer topography grouped by ICD-10 grouping over time
19	Cancer+/HIV- vs. Cancer+/HIV+	Projection of cancer topography grouped by ICD-10 grouping
20	Cancer+/HIV- vs. Cancer+/HIV+	Cancer occurrence grouped by entity
21	Cancer+/HIV- vs. Cancer+/HIV+	Cancer occurrence grouped by entity over time
22	Cancer+/HIV- vs. Cancer+/HIV+	Projection of cancer occurrence grouped by entity
25	Cancer+/HIV- vs. Cancer+/HIV+	Metastasis occurrence
31	Cancer+	Sequence in presumed HIV / Cancer / Metastasis / AIDS onset
Care Characteristics		
5	All main subgroups	Count of admissions per patient
6	All main subgroups	Mean length of stay per patient
Therapy		
23	Cancer+/HIV- vs. Cancer+/HIV+	Occurrence of cancer therapy modalities
24	Cancer+/HIV- vs. Cancer+/HIV+	Count of chemotherapy sessions
27	Cancer+/HIV- vs. Cancer+/HIV+	Occurrence of complications after chemotherapy
28	Cancer+/HIV- vs. Cancer+/HIV+	Time from chemotherapy to complication
32	Cancer+/HIV-	Sequence of cancer therapy modalities
33	Cancer+/HIV+	Sequence of cancer therapy modalities
Outcome		
26	Cancer+/HIV- vs. Cancer+/HIV+	Time from presumed cancer to presumed metastasis onset
29	Cancer+/HIV- vs. Cancer+/HIV+	Death after chemotherapy
30	Cancer+/HIV- vs. Cancer+/HIV+	Discharge reasons



5 Study Data

5.1 Data Generation

Primarily, data accumulated in the context of a federal law called *Krankenhausentgeltgesetz* (KHEntgG) is used to conduct this study. The KHEntgG requires all German hospitals to transmit the so-called §21-data-set to a semi-public institute (InEK GmbH) under management of central health system organizations.

For more information, see [here](#).

5.2 Data Storage and Administration

The data to be analyzed in this project is stored and administered by Data Integration Centers (DIC) of the participating university hospitals. No individual-level patient data will be transmitted (see Section on [Federated Analysis](#)). For a detailed insight into the requested Study Data see Chapter [Data Selection](#).

5.3 Federated Analysis

This study applies methods of Federated Data Analysis, with the following key consequences:

- Individual-level data is solely accessed by institutions of the participating sites.
- An analytic procedure (usually in the form of an executable Analysis Script) is provided to the sites by the Project Manager.
- The analytic output (usually in the form of aggregated data) is transmitted to the Project Manager

5.4 Data Privacy and Security

For individual-level data, the following applies: * It is pseudonymized * No individual-level data accessed in this study will be transmitted outside of the participating sites

For aggregated data, the following applies: * Various automated and supervised measures are put in place to minimize risk of re-identification * All files encrypted

5.5 Study Participant Consent

Since

5.6 Meta Data

6 Administration

6.1 Ethics Committee Votes

6.2 Use and Access Request

7 Roadmap

