FungiScope *Candida* Campaign

Prof. Oliver A. Cornely
Dr. Danila Seidel
Dr. Jon Salmanton-García

FUNGISCOPE
CANDIDA INFECTION REGISTRY

CANDIDA
Working Group of the ECMM & ISHAM

26 September 2025 Version 1.2

Contents

Background

Invasive candidiasis and candidemia (IC/C) are severe infections that can potentially be fatal, especially in hospitalized patients.[1,2] The epidemiology of IC/C is continuously evolving and is marked by an increasing prevalence of non-*albicans Candida* species, including *C. glabrata*, *C. parapsilosis*, and *C. auris*.[3] These species often present greater challenges in treatment compared to *C. albicans*, leading to extended hospital stays and higher mortality rates.[1,2] Moreover, there is a rising incidence of acquired resistance to antifungal agents like fluconazole and echinocandins in various species, such as *C. glabrata* and *C. parapsilosis*.[2,3] *Candida auris*, in particular, is a multidrug-resistant fungus that has emerged as a major global health threat recognized in the WHO priority list of fungal pathogens. It can cause outbreaks in healthcare settings and diagnosis of *C. auris* is particularly challenging hampering timely and adequate treatment.[4]

FungiScope® is an international retrospective registry collecting clinical cases of IC/C, with the primary objective of gathering comprehensive data on the epidemiology, risk factors, treatment, and outcomes of these infections.[5] This information can be instrumental in gaining a deeper insight into the current global management of such cases. Additionally, it can assist in the development and implementation of more effective prevention and treatment strategies or adherence to international management guidelines.[2]

Study Objectives

- Collect anonymized patient courses with invasive *Candida* infection retrospectively
- Investigate long-term epidemiology of invasive *Candida* infection
- Assess the effectiveness of antifungal treatments in light of new approved antifungals on the market and with globally increasing resistance
- Promote scientific exchange

Patient Inclusion Criteria

Mandatory:

- Confirmed diagnosis of candidemia and/or invasive candidiasis
- Patient age 18 or older
- Three months follow-up (for survivors)
- Availability of medical records
- With the use of newly approved antifungal agents, patients treated with respective drugs must be reflected in the number of overall documented cases

Optional:

- Fungal isolates to be send to a national or regional central lab.

Study Duration and Region

Study Start: January 1, 2024
Study End: December 31, 2026
Region: initially Europe, USA

Your Participation is Important:

Only together can we contribute to improving the management of invasive *Candida* infections. We will collaboratively publish results in high-impact scientific journals. Participation will allow you to become part of our international research network and together guide healthcare professionals in making informed decisions for antifungal treatment, further improving patient outcomes globally.

How to participate

Participating sites will include any number of cases of candidemia or invasive candidiasis diagnosed between 2024 and 2026. Anonymized and retrospective clinical data are collected via an online questionnaire (www.carelane.io, Carelane GmbH, Germany). Cases entered by the site will be accessible by the respective site. A designated team of data scientists and infectious disease specialists will review the cases for completeness and validity.

The following core data set will be collected (anonymized, retrospective data entry):

1 Epidemiological data: country, institution, level of care of the institution, catchment area

2 Demographic data: age-group, sex, ethnicity

3 Data of fungal infection: year of infection, species identification, co-infections with other fungi, clinical characteristics upon diagnosis

4 Data of concomitant diseases: diagnosis, duration of disease, current status and treatment

5 Potential risk factors for developing fungal infection: immunosuppressive therapy, chemotherapy, biopharmaceuticals, use of corticosteroids, radiotherapy, solid organ or human stem cell transplantation, chronic pulmonary disease, diabetes mellitus, renal failure and dialysis, trauma and major surgery, HIV/AIDS, neutropenia, mucositis, and other risk factors

6 Antifungal prophylaxis, if given: drug, route, dose, duration prior to diagnosis of invasive fungal infection

7 Diagnostic measures and findings (CT, MRI, endoscopy, ultrasound, micro- and molecular biological analyses, pharmacological analyses)

8 Antifungal treatment: drug, route of administration, dose, drug levels, duration, details on adverse reactions including start and stop day, relation to the antifungal drug and measures taken where applicable, and treatment outcome

9 Treatment response at day 14, 28, 42, 84 and status at most recent follow-up

10 Cause of death, autopsy results if applicable

Informed consent

As of the ethical approval of the study, an informed consent is not required due to the retrospective and anonymized study design ().

Authorship policy

Authorship will be available to every individual and center that is contributing clinical data or otherwise makes substantial contributions to the study. Authorship criteria adhere to established publication guidelines, such as those outlined by the International Committee of Medical Journal Editors (ICMJE). The order of authorship will reflect the level of contribution, ensuring transparency and recognition of collective efforts. FungiScope® is committed to promoting collaboration, maintaining academic integrity, and fair recognition for all contributors.

References

1 Egger, M. *et al.* Predictors for Prolonged Hospital Stay Solely to Complete Intravenous Antifungal Treatment in Patients with Candidemia: Results from the ECMM Candida III Multinational European Observational Cohort Study. *Mycopathologia* (2023). https://doi.org:10.1007/s11046-023-00776-4

2 Hoenigl, M. *et al.* Guideline adherence and survival of patients with candidaemia in Europe: results from the ECMM Candida III multinational European observational cohort study. *Lancet Infect Dis* **23**, 751-761 (2023). https://doi.org:10.1016/s1473-3099(22)00872-6

3 Arendrup, M. C. *et al.* European candidaemia is characterised by notable differential epidemiology and susceptibility pattern: Results from the ECMM Candida III study. *Journal of Infection* **87**, 428-437 (2023). https://doi.org:https://doi.org/10.1016/j.jinf.2023.08.001

4 Giacobbe, D. R. *et al.* Recent advances and future perspectives in the pharmacological treatment of Candida auris infections. *Expert Rev Clin Pharmacol* **14**, 1205-1220 (2021). https://doi.org:10.1080/17512433.2021.1949285

5 Seidel, D. *et al.* FungiScope(™) -Global Emerging Fungal Infection Registry. *Mycoses* **60**, 508-516 (2017). https://doi.org:10.1111/myc.12631

Contact information

Institute of Translational Research | CECAD Cluster of Excellence | University of Cologne

Infectious Diseases | Department I of Internal Medicine | University Hospital Cologne

ECMM Diamond Excellence Center | www.ecmm.info

Herderstrasse 52 | 50931 Cologne

Prof. Oliver A. Cornely MD, FECMM

Principle Investigator

Email: Oliver.Cornely@uk-koeln.de

Phone: +49 221 478 85523

Dr. Danila Seidel, PhD, FECMM

Scientific Lead

Email: Danila.Seidel@uk-koeln.de

Phone: +49 221 478 97343

Dr. Fiona Stewart, PhD

Project Manager

Email: Fiona.Stewart@uk-koeln.de

Phone: +49 221 478 67662

Natalia Vasenda, M.Sc.

Project Manager

Email: Natalia.Vasenda@uk-koeln.de

Phone: +49 221 478 67668

FUNGISCOPE CANDIDA INFECTION REGISTRY

CANDIDA Working Group of the ECMM & ISHAM

Annex 1 Data Classification: EU ‘Anonymized’ vs US Limited Data Set

EXPLANATORY NOTE: DATA CLASSIFICATION AND REGULATORY CONTEXT

Subject: Reconciliation of "Anonymized Data" (EU/Protocol) vs. "Limited Data Set" (US/HIPAA)

1. Context
The FungiScope® Study Protocol (Section 9.1) states that data collection is performed "anonymously". However, for US sites subject to HIPAA, the data transfer is governed by a Data Use Agreement (DUA) for a Limited Data Set. This note clarifies how these definitions coexist under their respective legal frameworks.

2. Classification under EU Law (Recipient Perspective)
Under the General Data Protection Regulation (GDPR) and recent case law (specifically the CJEU decision in Single Resolution Board vs. EDPS), the classification of data is relative to the party holding it.

- **Protocol Definition:** The Registry (Recipient) defines the data as **anonymous** because it does not receive direct identifiers (names, MRNs) and holds no key or pseudonym map that would allow it to re-identify patients.

- **Legal Basis:** If the recipient does not have the legal means or reasonable technical ability to re-identify the data subject, the data is considered non-personal (anonymous) for that recipient.

- **Conclusion:** Therefore, from the European Registry’s perspective, no GDPR Article 28 "Processor" agreement is required, as they are not processing personal data on behalf of the site, but receiving anonymous data as a Third Party.

3. Classification under US Law (Provider Perspective)
Under HIPAA, the classification of data is absolute based on the data elements present.
- **Limited Data Set (LDS):** The study requires specific dates (Year of Infection, dates of treatment response) and geographic/institutional data (Institution Name, Catchment Area) for epidemiological analysis.

- **Conclusion:** Because these indirect identifiers are present, the data does not meet the "Safe Harbor" standard for de-identification. Consequently, US sites must treat the transfer as a **Limited Data Set**, requiring a Data Use Agreement (DUA) rather than a Business Associate Agreement (BAA).

4. Technical Assurance (Carelane Platform)
The security architecture of the Carelane platform supports this "Relative Personal Data" separation:
- **Encryption Keys:** Encryption keys for identifiable data are generated uniquely per study site. The Registry (Sponsor) has no access to these keys.

- **Data Isolation:** The Provider retains sole control over the re-identification key (the code list), ensuring the data remains effectively anonymous to the Recipient while retaining its utility for the Provider.