

**Procedure Register**  
**according to Section 4g (2) of the German Federal Data Protection Act**  
**(Bundesdatenschutzgesetz - BDSG)**

**1 Name of the responsible body**

Alcedis GmbH

**2 Managing board, data processing manager**

**2.1 Managing board**

Mrs. Dr. Elke Heidrich-Lorsbach  
Mr. Michael Lorsbach

**2.2 Data processing manager**

Mr. Andreas Gareiß

**3 Address of the responsible body**

Alcedis GmbH  
Winchesterstraße 3  
35394 Gießen  
Germany

**4 Purpose of data collection, processing or use**

As an independent clinical research organisation Alcedis supports medical work groups, hospitals and pharmaceutical companies in implementing projects of clinical research and documentation. Integrative parts are flexible data entry and management systems - adjusted to the needs - for clinical trials and non-interventional studies. Alcedis provides and hosts these systems and also performs reports as ordered by customers.

Alcedis implements clinical studies of phases (I), II-IV according to international standards (ICH, FDA) in different indications with focus on oncology.

The purpose of collecting, processing and using personal data consists in customer acquisition, product consulting, processing of customer orders, customer relationship management and product marketing.

Collecting, processing and using personnel data for own purposes occur only if it is required for the employment relationship and as regulated by law and to fulfil legal obligations.

## **5 Description of the group of people affected and their data or data categories**

### **5.1 Groups of people**

- Employees
- Applicants for employment
- Customers
- Suppliers
- Interested parties or people

### **5.2 Data categories**

- Personnel data of employees
  - Personnel master data (e.g. name, address, date of birth, bank account, tax class, number of children, religious affiliation, health insurance company)
  - Details of professional qualification such as CV, application documents, testimonials - including training courses for continuing further professional education (training certificates)
  - Dates of joining and leaving the company
  - Data of salary and wage payments
  - Data of pension and social insurance
  - Employment contracts
  - Results of staff appraisals, warning letters, certificates for current professional qualifications
  - Data for personnel administration (working time model, recording of working time, holiday planning, sick notes)
- Applicants for employment
  - Contact details
  - Data of the professional career in accordance with the current application procedure (evaluation sheets, protocols of job interview)
- Suppliers
  - Master data maintenance (contact and address data)
  - Offers and contracts
  - Delivery notes, invoices
  - Appointment management

- Customers / Orderers
  - Master data maintenance (contact and address data)
  - Offers and contracts
  - Invoices
  - Appointment management
  - Web hosting data
  - Data capture for studies
    - Patient details: pseudonym, clinical data, e.g. diagnoses, therapies, lab data according to study protocols
- Investigators / physicians and assistance staff
  - Master data maintenance (contact and address data)
  - Curriculum vitae
  - Details of professional qualification
  - User account data to systems for study data capture
- Interested parties or people
  - Master data maintenance (contact and address data)
  - Appointment management
- E-mail correspondence of employees
  - All employees have a specifically e-mail account, who should be used only for business purposes.
  - All e-mail data are archived in an audit-proof manner

## **6 Data recipients**

- Social insurance agencies, fiscal authorities
- Customers / Orderers
- External service providers
  - Friedrich Kurz GmbH, Walter-Zapp-Str. 4, 35578 Wetzlar, Germany: File archiving, archiving of magnetic tapes of data backups
  - Tax Chancellery Gerhard & Sinke, Bahnhofstraße 32, 35305 Grünberg, Germany: Financial accounting, payroll accounting
  - ad-acta Data privacy & Recycling GmbH, Hüttenweg 8, 35398 Gießen, Germany: file/document destruction

- Sylphen GmbH & Co. KG, Philipp-Reis-Str. 4, 35398 Gießen, Germany: Maintenance and IT administration of servers and network components including backup recovery and remote maintenance

## 7 Time limits for data deletion

- Payroll data: 10 calendar years according to Section 147 of the German Fiscal Code
- Personnel data: 10 years after leaving the company, if there is no legitimate interest in further storage  
  
Warnings: after 2 years, if there is no legitimate interest in further storage  
  
Staff appraisals, evaluations: after 2 years, if there is no legitimate interest in further storage  
  
Sick notes: Usually after 4 years, if there is no legitimate interest in further storage
- Applicant data: Not later than six months after completion of the job application procedure, unless the applicant has given his/her consent for further use, see Section 15 and 21 of the German General Act on Equal Treatment [*Allgemeines Gleichbehandlungsgesetz – AGG*]
- Customer data: The time limits for deletion of customer data (all data, which are recorded and processed in clinical trials) are governed by the legal requirements (Section 42 of the German Medicinal Products Act [*Arzneimittelgesetz - AMG*], Section 12 of the German Medical Devices Act [*Medizinproduktegesetz - MPG*], Section 10 of the German Ordinance on Clinical Trials of Medical Devices [*Verordnung über klinische Prüfungen mit Medizinprodukten - MPKPV*], see Standard Operation Procedure (SOP) GE02-A5: Overview of Archiving Obligations) and generally amount from 10 to 30 years or they are represented by agreed customer requirements.

## 8 Planned data transmission to third countries

- If customers are located in third countries, personal data are stored and processed using pseudonyms and transmitted to them.
- A planned data transmission of personal data to third countries happens otherwise only to the subsidiary Alcedis Inc. based in New York City, USA, in so far as project-specific data are concerned, which have to be used within the context of a contract for services with the respective clients, according to the contract to the extent necessary for this.