



## Basic information about Institute of Education I.E.

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### About

I.E. was founded in 1998, since 2002 biostatistics and data management are main field of activity. In 2006 I.E. obtained ISO 9001:2000 certificate applicable to “Statistical analyses’ of medical data, processing the medical data”. Certification was obtained from Lloyd's Registry Quality Assurance.

### Activities

#### Data Management

- Database programming
  - Internet databases
- Data Entry
- Dataset cleaning
  - Medical review of the data
  - Coding of Adverse Events
  - Query management
- Paper CRF printing
- Preparing of randomization lists

#### Biostatistics

- Sample size planning
- Analysis of all kinds of medical data
- Report writing

#### Education

- Courses in different aspects of statistical analysis of medical data and data management.

#### Medical writing

- Protocol preparation
- Preparation of documents such as ICF, CRF
- Report writing
  - Including reports according to EMEA CPMP/ICH/137/95 guidelines



## Team

Basic team: 4 employees (two biostatisticians, medical writer, data manager)

Daniel Rabczenko, PhD (CV included) is responsible for work coordination and use of appropriate methods in analysis

Anna Sozańska-Solak, MD (CV included) is responsible for medical part of projects

## Experience

Realization over 70 projects for:

- MTZ Clinical Research data management, statistical analyses over 25 projects
- ROCHE Poland, data management, statistical analyses, sample size planning, preparation of CRF on the protocol basis
- Sanofi-Aventis
- Polpharma data management, statistical analyses,
- Synevo Poland
- MedSource Poland
- CRO Poland
- Scientific institutions:
  - Medical Academies of Warsaw and Białystok
  - Institute of Oncology
  - Institute of Geography and Spatial Organization
  - Center for Ecological Research
  - Institute of Psychiatry and Neurology
  - National Tuberculosis and Lung Diseases Research Institute



## Quality

I.E. quality system is based on guidelines of Society for Clinical Data Management (Good Clinical Data Management Practices Version 4.0). In 2006 I.E. obtained ISO 9001:2000 certificate applicable to “Statistical analyses’ of medical data, processing the medical data”.

### List of procedures:

Data Management & Statistics	System procedures
DM001 Data Management Plan Preparation	PS001 Protection of Confidential Information
DM002 Database creation	PS002 Principles of keeping and Archiving of Documentation
DM003 Admission and return of data	PS003 Management of Computer System
DM004 Data Entry	PS004 Supervision of Documentation
DM005 Database Closure	PS005 Supervision of Records
DM006 System of queries preparation	PS007 Improvement of Quality Management System
DM007 Statistical Analysis	PS008 Dealing with Incompatibilities
	PS009 Trainings and training documentation

### Software we use:

#### Statistical analyses

SPSS

SAS

R

Other: EpiInfo

#### Sample size planning

StudySize 2.0

PS Power and Sample Size Calculations 2.1.30

#### Database & Data Entry

SPSS Data Entry Builder

SPSS Data Entry Station

EpiData

MS Access

#### Dictionaries

ICD-10

MedDra

### Contact information

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Attachment 1: ISO Certificate



**CERTIFICATE OF APPROVAL**

This is to certify that the Quality Management System of:

**Instytut Edukacji I.E. Sp. z o.o.  
Warszawa, Poland**

has been approved by Lloyd's Register Quality Assurance  
to the following Quality Management System Standards:

**ISO 9001:2000**

The Quality Management System is applicable to:

**Statistical analyses' of medical data, processing  
the medical data.**

Approval  
Certificate No:  
GDK6000016

Original Approval: 5<sup>th</sup> January 2007

Current Certificate: 5<sup>th</sup> January 2007

Certificate Expiry: 4<sup>th</sup> January 2010



Issued by: Lloyd's Register (Polska) sp. z o.o.  
for and on behalf of Lloyd's Register Quality Assurance Limited



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This document is subject to the provision on the reverse  
Lloyd's Register (Polska) sp. z o.o., ul. Marynarki Polskiej 177, 80-958 Gdańsk, KRS 0000117768  
This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.  
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001  
Macro Revision 13