



healthy data

WHO WE ARE?





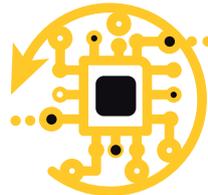
Our vision is HEALTHY DATA. We manage and analyze data in clinical research projects, which we also help to organize. We have developed our own solution for clinical data management, namely the electronic-data-capture system CLADE-IS, which contains a module for risk-based monitoring based on machine learning algorithms. We were established as a spin-off of Masaryk University and we succeeded in transferring the results of R&D from the academia to the application in society.



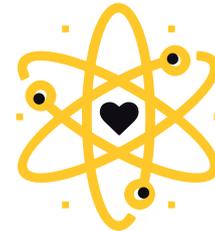
**data
management**



**data
analysis**



**project
management**



**information
technologies**

IBA - GLOBAL SERVICE

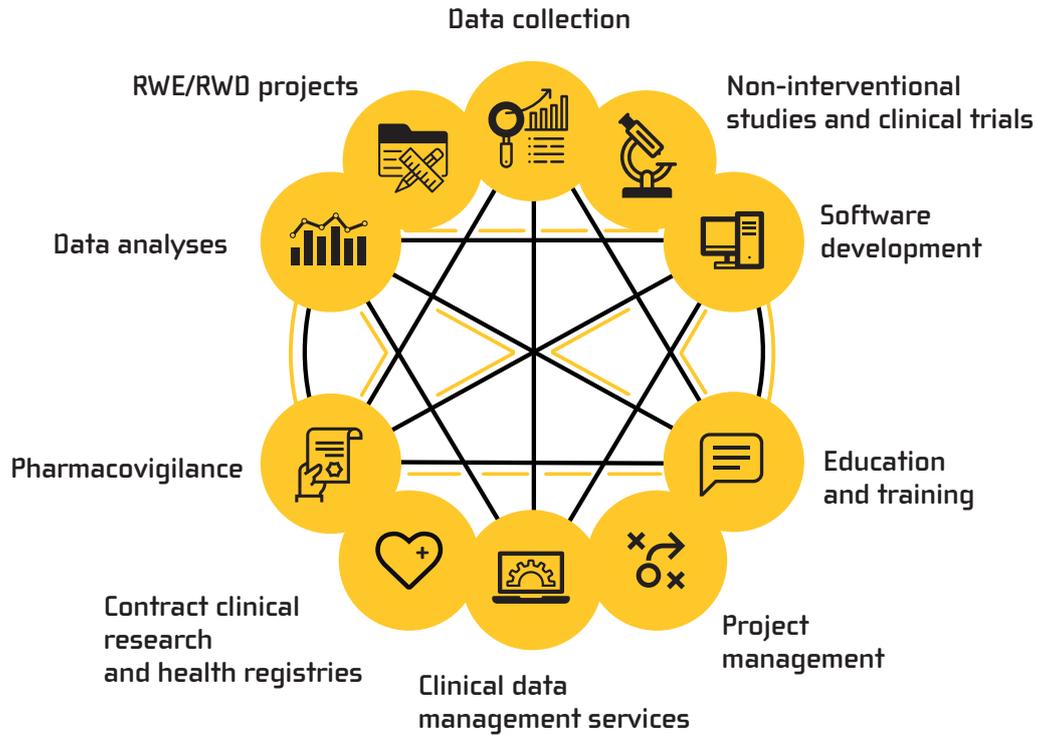
IBA develops and runs information systems for collection, validation and analysis of clinical data, mostly by means of web-based technologies.

IBA provides complete services in clinical research projects – non-interventional studies and clinical trials. The contract research activities include project design, CRF/eCRF proposal, document completion and communication with regulatory authorities, ensuring expert guarantee by professional medical societies, data reporting and study monitoring.

The Data Analysis department at IBA has extensive experience in biostatistics, data science and data fusion.



Our focus



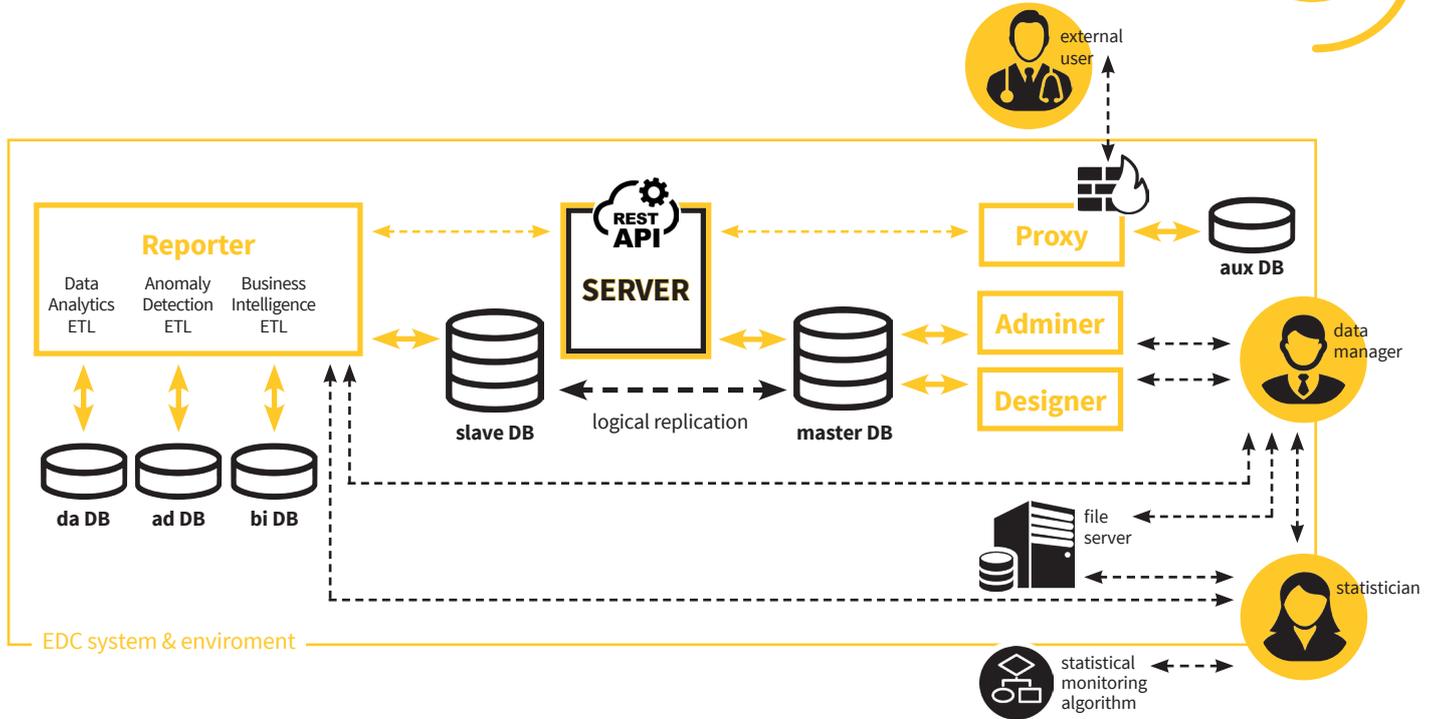
Centralized statistical monitoring means Healthy Data

The centralized statistical monitoring is the evaluation of study data carried out by team of experts on clinical data management and clinical biostatistics.

Statistical monitoring algorithms can be used on all variables that influence data quality.

- Statistical monitoring techniques are provided by CLADE-IS-Reporter, project statistician and project data manager.
- CLADE-IS Reporter facilitates data management and analysis with features towards complete study data export and data transformations that enable building data views for statistical monitoring, online visual analytics, etc.
- The statistical monitoring procedures are regularly performed by the assigned statistician on the data sets provided by the assigned data manager.





Quality Assurance

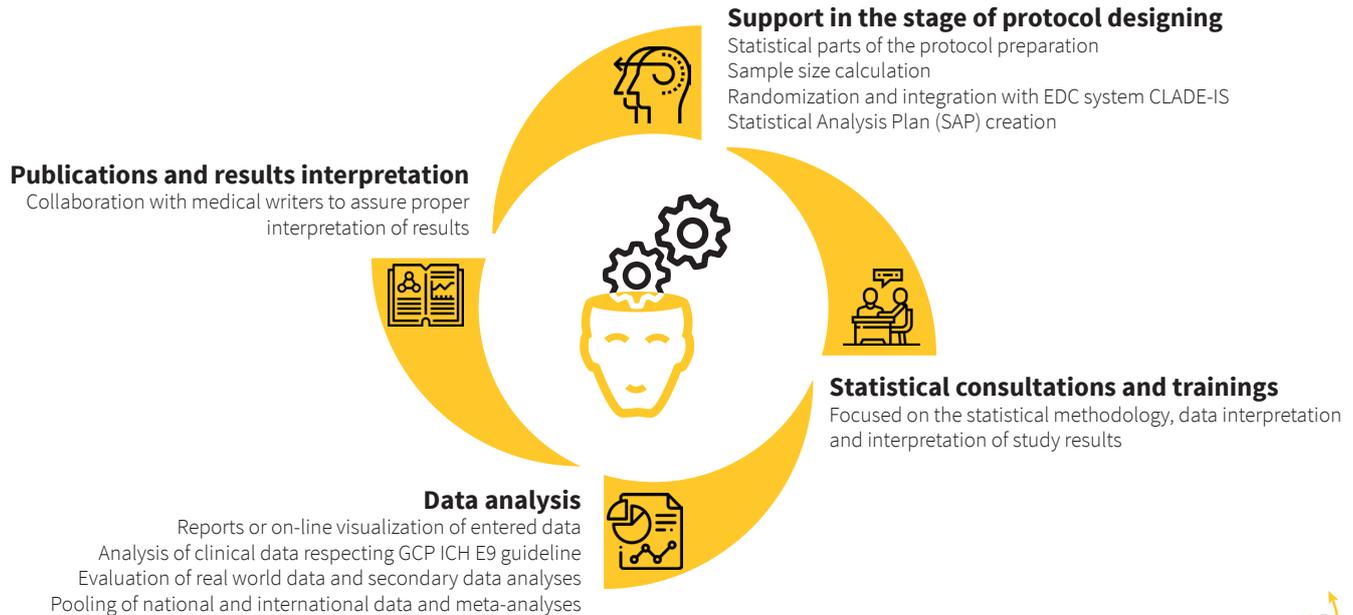
Institute of Biostatistics and Analyses Ltd (IBA Ltd) has implemented the integrated system of quality management in accordance with EN ISO 9001:2009 (quality management systems), and ISO/IEC 27001:2006 (information security management system). Our outputs and services are currently guaranteed by the ISO/IEC 27001 certificate and EN ISO 9001 certificate.

In addition to the above normative requirements, the IBA also integrates the requirements of good clinical practice and good pharmacoepidemiological practice into its quality system.



Data Analysis

IBA has a large and highly experienced team of biostatisticians and data analysts.



Medical Device Projects

Regulations (EU) 2017/745 of European parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Planning and design

- Study design
- Sample size evaluation
- Clinical investigation plan development

Study management

- Site feasibility
- CRF and eCRF creation
- Regulatory activities

Reports

- Monitoring reports
- Interim reports
- Final reports

Analysis

- Descriptive and explorative data analysis
- Interpretation of the results





Education and Training

IBA offers customized trainings in the field of data analysis and data management.

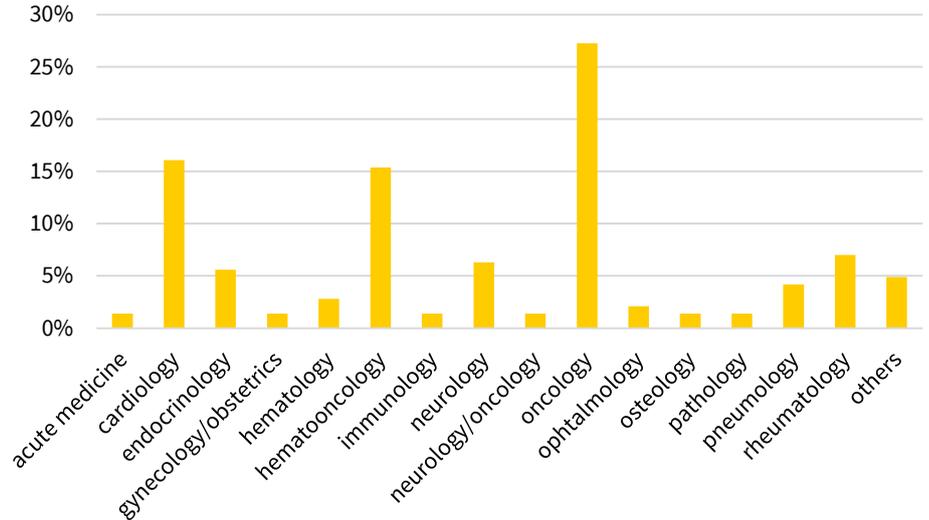
Customized trainings

- Trainings fully tailored to the needs of the client
- Trainings for the professional public
- Statistics training focused on the statistical methodology, data interpretation and interpretation of study results
- Data management training focused on eCRF creation, data quality and methodology

**> 50
trainings**

Implemented projects

**> 300
projects**

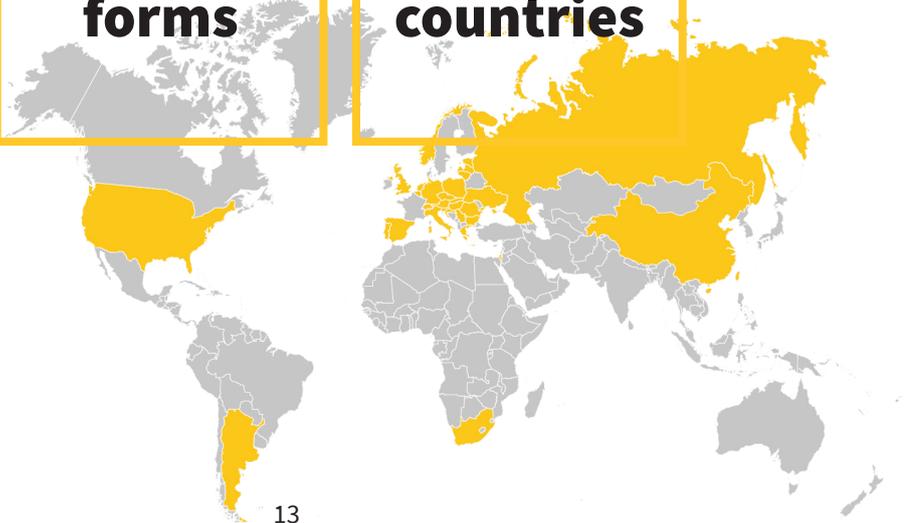




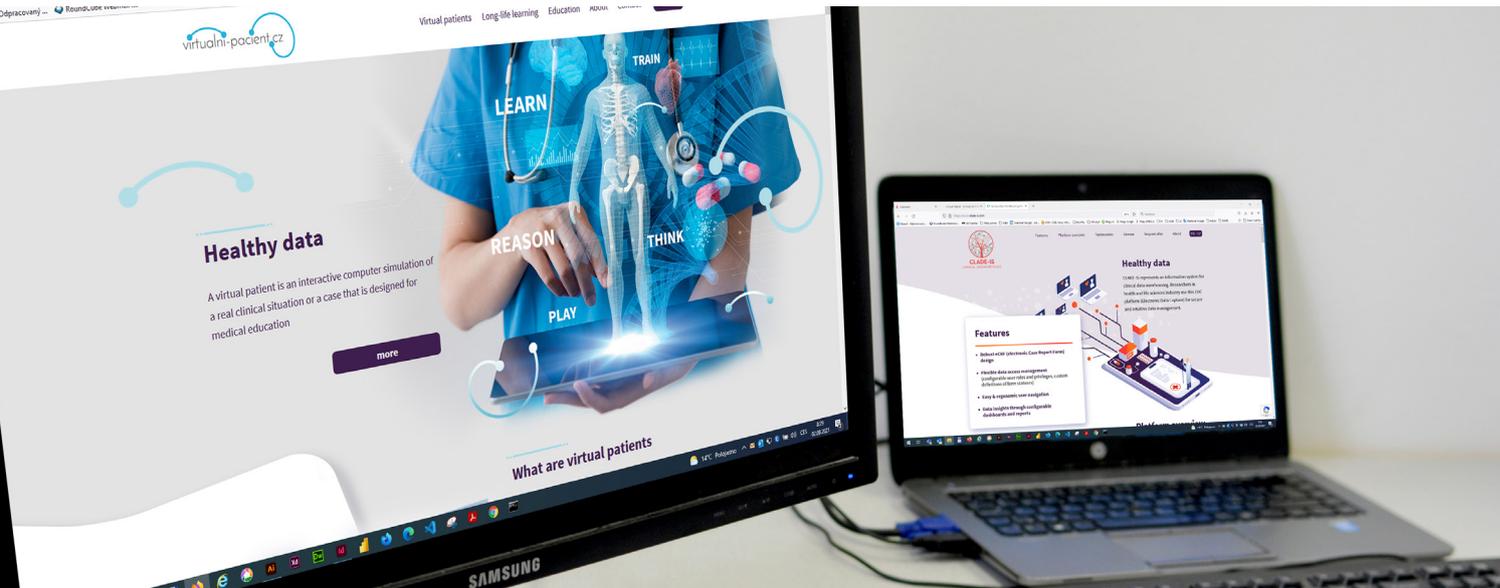
**> 170 000
patients**

**> 1 500 000
forms**

**> 25
countries**



OUR PRODUCTS





The software development department at IBA innovates IT solutions for intuitive and secure user experience.

Our in-house developed EDC system CLADE-IS represents the flagship within the company's product portfolio and related services. The main innovative potential of this product consists of algorithms for risk-based monitoring and a wide range of functions aimed at visual analytics to support clinical decision making.

Another product resulting from our software development is a virtual patient delivery system. The main value proposition of this product is scenario-based learning which brings gamification into continuous medical education and allows safe and low-risk decisions with a prompt feedback.

Virtual patient

Low-fidelity simulations for continuous medical education with low risk

A virtual patient represents an interactive computer simulation of a real clinical situation or a case that is designed for medical education. It is a learning modality that facilitates development of specific skills such as clinical reasoning, decision making and critical thinking.

Virtual patient delivery system

The underlying original web-based learning platform allows creating and presenting linear VPs enriched with imaging findings, multiple-choice questions and links to evidence-based medicine resources. In addition, it comes with a scoring system which brings the virtual patients closer to the field of serious games. The front-end component is underpinned with a responsive web design, which ensures easy and ergonomic user interface.

Reference project

LAURIE (virtual pAtients sUffeRiNg from schizophrenia, <https://www.laurie-project.com>) – this international project represents a low-risk approach to continuous professional development for psychiatrists using low-fidelity simulations of clinical cases. The presented set of virtual patients suffering from schizophrenia are inspired by real-world patients and present imaginary interactive stories. The LAURIE project extends on-line training opportunities for young psychiatrists and provides them with features of life-long learning gamification.

For more information and reference projects visit <https://www.vituali-pacient.cz>.





CLADE-IS

Clinical Data Management Software

CLADE-IS (CLinical Data warEhousing – Information System) represents an information system for clinical data warehousing. Researchers in health and life sciences industry use this EDC platform (Electronic Data Capture) for secure and intuitive data management.

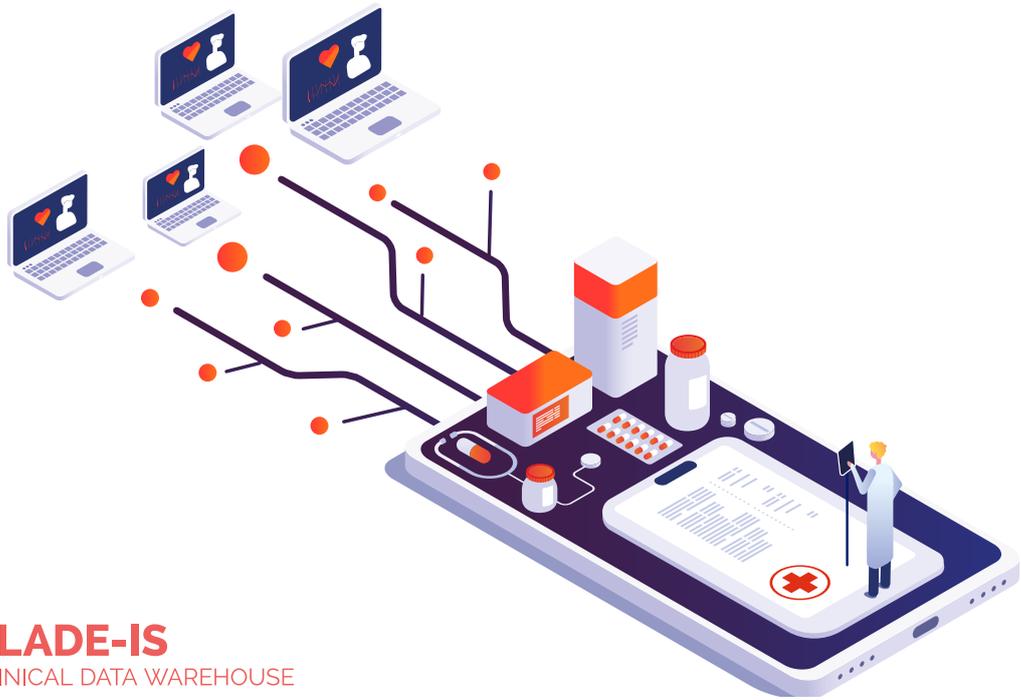
To date, the CLADE-IS has been implemented in hundreds of clinical centers where it serves numerous research studies, mostly clinical registries and other RWD projects. Therefore, this EDC system contains millions of authentic records of different origin. Such a huge set of real-world data made it possible to design, implement, and validate an original machine learning algorithm for detection of anomalous data. This feature helps numerous CROs and data in performing the effective risk-based monitoring.

For more information and testimonials visit: <https://www.clade-is.com>

Reference

Churová V et al. (2021): Anomaly Detection Algorithm for Real-World Data and Evidence in Clinical Research: Implementation, Evaluation, and Validation Study, *JMIR Medical Informatics* 7;9(5):e27172. doi: 10.2196/27172, <https://doi.org/10.2196/27172>.





CLADE-IS
CLINICAL DATA WAREHOUSE

OUR CLIENTS





SANDOZ A Novartis
Division

 **IPSEN**
Innovation for patient care

 **GILEAD**

 **Biogen.**

 **AOP ORPHAN**
FOCUS ON RARE DISEASES



 **Chiesi**

 **ACTELION**
A JANSSEN PHARMACEUTICAL COMPANY
of *Johnson & Johnson*



 **Celgene**

Lilly

 **BERLIN-CHEMIE
MENARINI**



MERCK

TEVA

 **gsk**
GlaxoSmithKline

 **sobi**



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