

2023 Offer

 **BIOSTAT**[®] | CRO

WWW.BIOSTAT.COM.PL

BioStat®

Who we are?

Leader on the Polish market in providing professional and innovative solutions in the area of clinical trials and observational studies, statistics, medical software, telemedicine and R&D.

Commercial research unit with status of a Research and Development Centre (R&DC) granted by the Minister of Entrepreneurship and Technology.

+18
years of experience

+70
experts

+2000
studies

+500
publications

+20
audits

BioStat®

Our clients

Over 50 cooperating entities.



Pharmaceutical
companies



Biotechnological
companies



Clinical Research
Organization (CRO)



Academic & scientific-
educational units



Medical universities



Hospitals, clinics



Scientific societies
and associations



Medical equipment
manufacturers



Individual clients
(scientists, KOLs, etc.)

BioStat®

Therapeutic areas

Projects implemented in various fields:

Oncology

Gastroenterology

Transplantology

Cardiology

Neurology

Allergology

Psychiatry

Neonatology

Diabetology

Pulmonology

Immunology

Andrology

Proctology

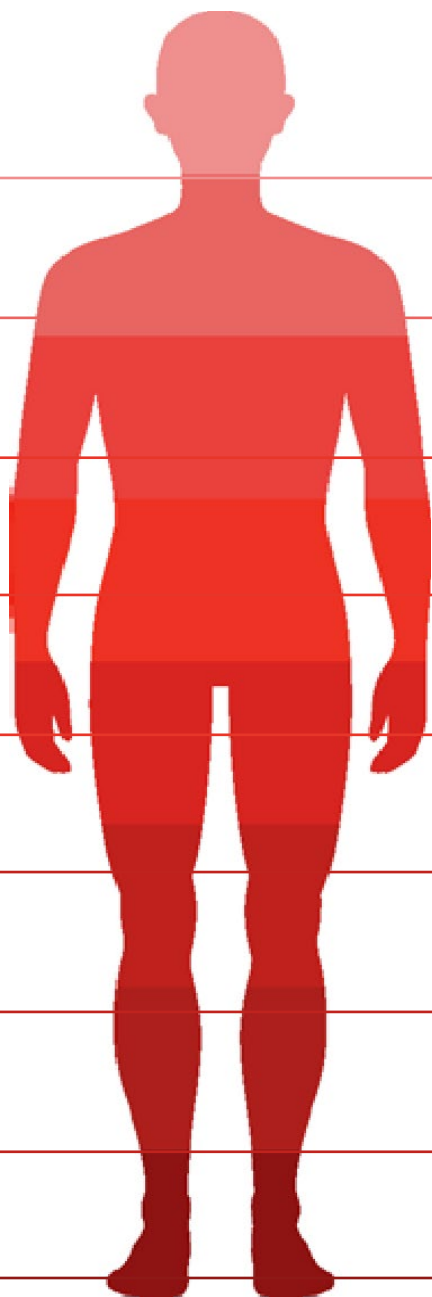
Dermatology

Ophthalmology

Rheumatology

Virology

Hematology



BioStat®

What we do?

Comprehensive services:



Clinical trials



Non-interventional
studies



Medical statistics



Data Management



eCRF.biz™ system



Market research and public
opinion surveys



Medical/telemedical
applications and platforms

BioStat®

Clinical trials

Commercial Clinical Trials (CCT) and Investigator Initiated Studies (IIS)

The range of support we provide for phase I-IV of clinical trials:

eCRF - Electronic Data Capture System, *EDC*

Interactive Web Response System, *IWRS*

Data Management, *DM*

Statistics, Analysis

Documentation

Monitoring/CRO support

Project Management

Counseling/consulting



BioStat®

Non-Interventional Study

We support our clients at every stage of work by offering comprehensive preparation and service of prospective and retrospective studies.

Study design

Preparation and consultation of complete study documentation

Contracting of sites

Contracting of Investigators (online contracts)

Preparation of application for Ethics Committees and

Competent Authority, obtaining approvals

eCRF preparation

Trainings

Comprehensive statistical service

Data Management

Supervision of adverse events reporting

Study monitoring

Study management and supervision of study

Statistics, analysis

Assistance in preparing publication of study results

Counseling/consulting

BioStat®

Other research projects



Patient's medical records

Post Marketing Surveillance, *PMS*

Real-World Evidence studies, *RWE*

Retrospective studies

Post Authorization Safety Study, *PASS*

Post Authorization Efficacy Study, *PAES*

Studies of an Rx-to-OTC Switch

Case-study research

Studies on dietary supplements

BioStat®

Medical statistics

One of the best statistical teams in Poland.

Statistical services for scientific and commercial research programmes in the field of biostatistics, statistical analyses, data mining and data management.

Statistical analyses in accordance with the requirements of the **Master Journal List**.
Statistical consulting.

Methods used:



R



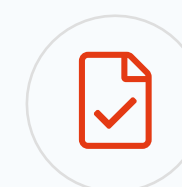
SPSS



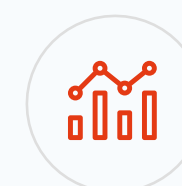
Python



Basic descriptive statistics



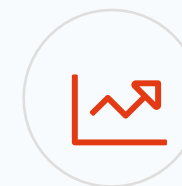
Verification of statistical hypotheses



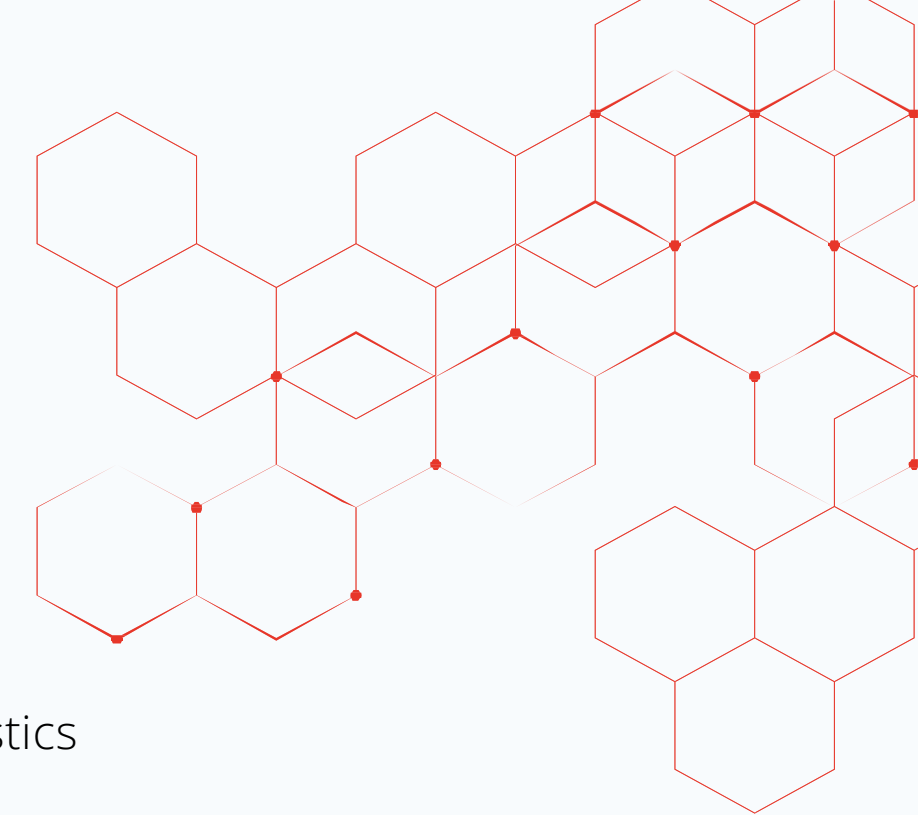
Interdependence analysis



Multidimensional analyses



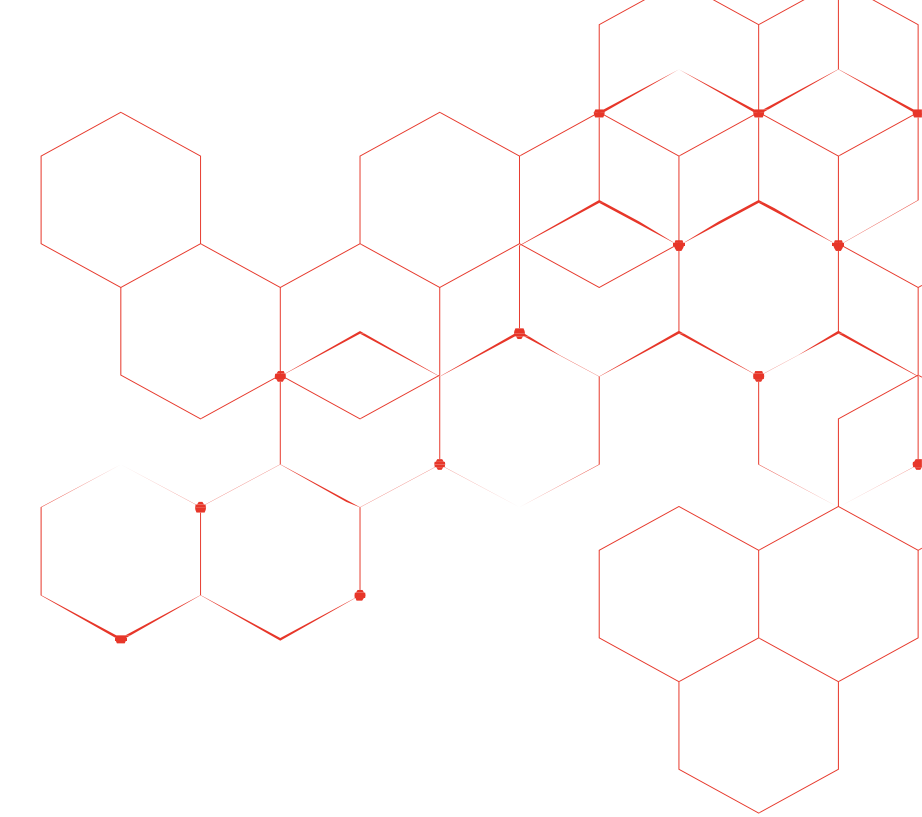
Evolutionary algorithms



BioStat®

Professional statistical services

Our experts will prepare every
methodological aspect of planned study.



DESIGNING THE STUDY:

- Sample size calculation
- Statistical justification
- Statistical Analysis Plan
- Statistical input to the Study Protocol
- Selection of variables and measuring scales
- Selection of randomization method, randomization list
- Choice of methods and statistical tests
- Statistical modeling

DATA COLLECTION:

- Database design and execution
- Preparation of data for statistical analysis
- Statistical and graphical presentation
- eCRFdesign

DATA PROCESSING

- Single and multidimensional statistical analyses
- Big data analyses
- Correlations, statistical models, tests
- Reports and interim analyses
- Survival analysis (Kaplan-Meier curves)
- Preparation of the final statistical report
- Support for CSR creation and publication

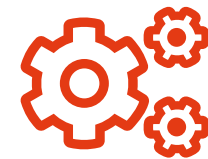
BioStat®

Data Management

Compliance with international standards

(Good Clinical Data Management Practices, Version 4, October 2005, Society for Clinical Data Management).

Good Data Management is the key
to the success of the study.



Configuration,
validation, cleaning
and database blocking



Database testing,
UAT



Development/update/
validation of eCRF



Database Management



Ongoing quality control



User account
management



Documentation



Queries management



Reconciliations



Edit checks



Formal and statistical
verification



Identification of outliers



Data management
services on external EDC
systems



Cooperation with
international research
teams

BioStat®

eCRF.biz™

Electronic Data Capture System, *EDC*

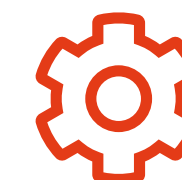
The platform is recommended by professionals on the Polish market.

MODERN TECHNOLOGY FOR BIG DATA

The world is changing, and so are we.



Compliance with the guidelines **FDA Title 21 CFR Part 11**



Original BioStat® system (no additional license)



Interactive Web Response System (IWRS)



The possibility of integration with laboratories



Unique design of each study



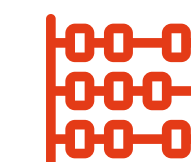
Unlimited number of studies



Interoperable and scalable platform



Integration with the online contracting system



Full validation and specific tests

BioStat®

eCRF.biz™ functionalities

Modules:

Data queries

Randomization

Drug management

Reports

Analytics

Online contracts signing

Audit trail

Comments

Notification

User account management

Documentation

Deviation log

MedDRA dictionary integration

ePRO – electronic Patient Reported Outcomes

The success of any study depends on the excellence of the developed eCRF and well provided data management services.

BioStat®

eCRF.biz™ benefits

We optimize research processes by providing the best and proven solutions.

We are moving clinical trials and observational studies into a digital world.

Remote access from any web browser
without installing software.

24/7 data availability

Configurability and scalability of the eCRF
system

Different access levels (e.g. Sponsor, Monitor,
Medical Monitor, Programmer, Data Manager,
Drug Supplier, Investigator, Co-Investigator,
etc.)

Generating printouts directly from the eCRF
system

Fast data transfer from external sources,
integration with laboratories

Notifications (e.g. about adverse events,
about opening and closing cohorts, etc.)

High level of security (logical, physical and
system security)

Real-time data backup

BioStat®

ePRO

electronic Patient Reported Outcome, *ePRO*

Our digital solutions are an alternative to paper patient diaries.

How does BIOSTAT ePRO work?



Remote data capture from the patient's device



Data synchronization with eCRF.biz (EDC)



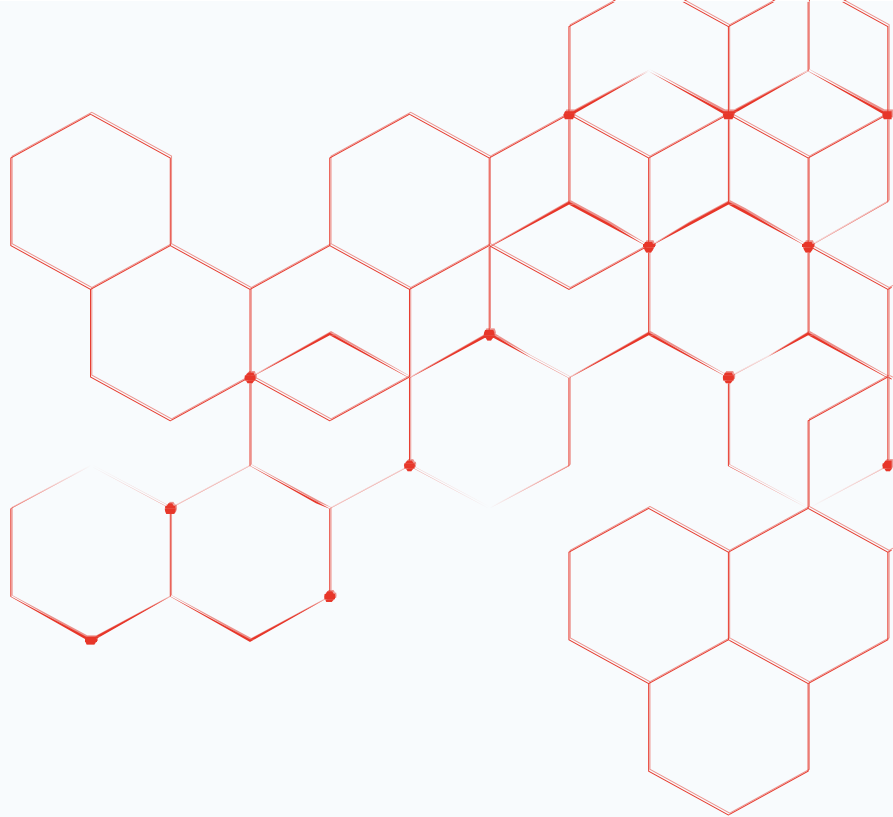
The ability to collect data at the site and at home



Improving patient experience and reducing their burden



Proactive and safe data collection



Benefits:

- Integrated with the eCRF.biz™ electronic data capture system
- Saves time and money
- Higher level of patient compliance with medical recommendations
- Improving data quality
- Software based on the web application (the ability to prepare mobile applications)
- Compliance with **21 CFR Part 11** guidelines
- Site visits reduction
- Real-time access to patient data
- Automatic notifications
- A wider range of collected data

BioStat®

Our technological solutions:



eCRF – electronic data capture
system in clinical trials



Electronic Medical Records
System



Online platform for
medical consultation



Authorized service to
collect approvals and create
forms



Application for
surveying clients



Consumer Panel for
Surveys



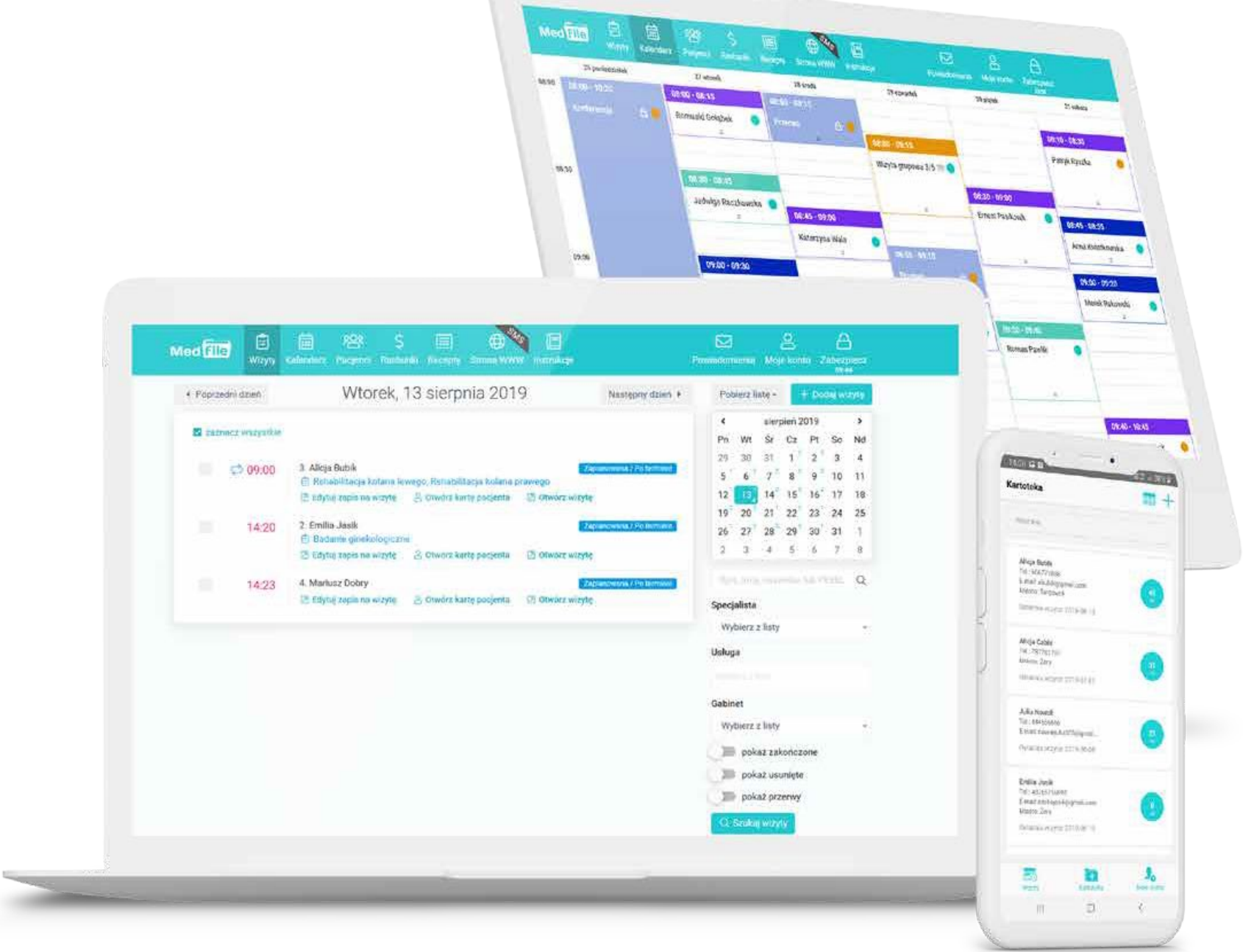
Research software:
CATI, CAWI, CAPI



Comprehensive solutions for the management of a doctor's and physiotherapy office.

Functions

-  eWuś
-  e-Sick leave
-  e-Prescription
-  Visit card
-  e-Referrals
-  e-Patient's file



- Online visit booking
- Integration: Docplanner, Google Calendar
- Telemedicine / online consultations
- Payment services (bills, invoices)
- Database import/export
- Intelligent databases (self-suggestions)
- Mobile applications (iOS, Android)
- SMS notifications
- Clinic website
- Work schedule/visit schedule
- Modules for specialist
- Warehouse
- Surveys and forms

BioStat®



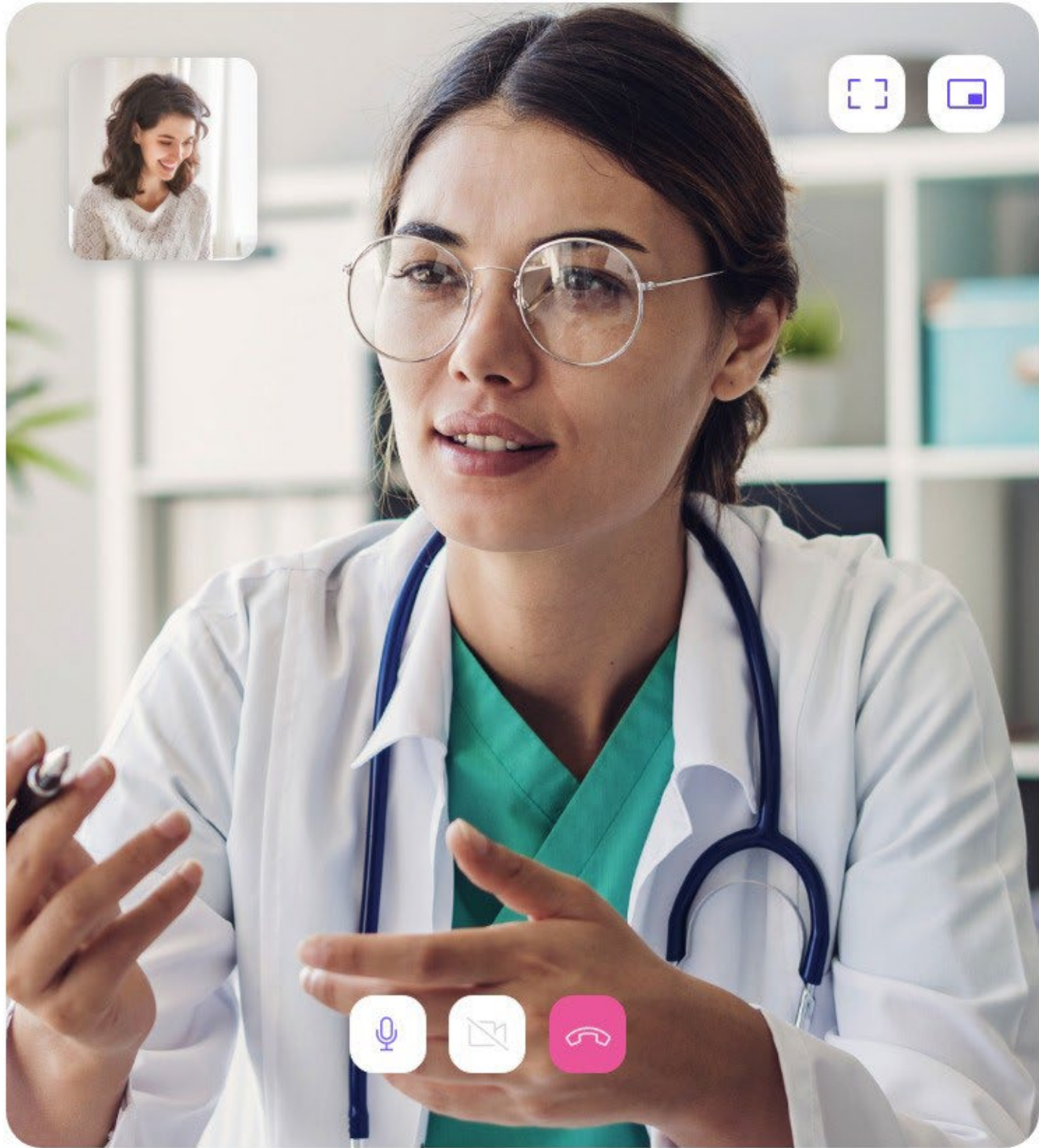
Telemedicine platform - online consultation

Funkcje systemu

- | | |
|------------------|-----------------------|
| ✓ e-Clinic | ✓ e-Sick leave |
| ✓ e-Consultation | ✓ e-Consilium |
| ✓ e-Visit | ✓ Patient e-account |
| ✓ e-Prescription | ✓ Patient e-signature |

Medfile® EDM integration

Telemedicine connects professionals with patients online.



Opis

Dzień dobry, odczuwam od rana z...
sobie przed chwilą ciś...
Czuję również c...

lek. Anna Kwiatkowska
Dzień dobry,
Pani Aleksandro, objawy...
Czy odczuwa Pani równ...
np. kołatanie serca?

Tak, rów

BioStat®

MedSign

Authorized patient consent

Authorized service to collect approvals in accordance with the General Data Protection Regulation. A simple way to obtain the required signatures and maintain relationships with customers.

SSL encryption certificates

Cryptographic data protection measures

Designated Personal Data Inspector

Integration with CRM

Improving telemedical consultation

Pursuant to Article 245 of the Code of Civil Procedure, a document drawn up in writing and in electronic form constitutes evidence that the person who signed it has made a declaration within the document.



Shortening the time for formal matters, increasing the duration of specialist consultations.

Creation and any configuration of forms by a doctor

Patient filling in the forms by himself

Signature for the specialist services offered

BioStat®



A platform for creating, implementing and managing opinion and satisfaction surveys.

Fast and intuitive electronic survey.

Simplicity and usability
CATI, CAWI, CAPI methods
Easy configuration
Surveys of patients, clients

Easy distribution of questionnaires (e-mail, link on the website, social media)
Representative national trials
Reports/statistics
Benchmarks



Wróć do listy badań

Ankieta

Baza klientów

Panel Badanie Opinii

Statystyki

Ustawienia

Komentarze

Statusy

Rozszerzenia

Uprawnienia

Wielodostęp

Powiadomienia

Analiza próby

Przegląd odpowiedzi



Premium

Zwiększ swoje możliwości,
pozbądź się limitów

Kup subskrypcję

Regulamin

Przewodnik

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Panel Badania Opinii

Wielkość próby



Charakterystyka próby: Dowolne ☒ Wybierz

Płeć	Liczba	% Próby	Wiek
1. Kobieta	100 < >	50%	1. 18-29 lat
2. Mężczyzna	100 < >	50%	2. 30-39 lat

Rozpoczęcie realizacji

Dowolne ☒ Wybierz własny

12 Kwiecień, 2019

April 2017						
Pn	Wt	Śr	Czw	Pt	So	N
						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29
30						

Dane do

Nazwa fir

testowy

Imię*

testowy

Ulica*

testowy

Kod poczt

testowy



BioStat®



200.000+
panelists

150+ daily
new users

Rapid delivery (24h)

Reliability of the tests performed

Low survey cost

Full compliance with General Data Protection Regulation, *GDPR*

Up to date database of respondents

Badanie Opinii

Badania

Profil

Zaproś znajomych

Konrad Wallenrod✎

Liczba znajomych: 12Dostępne punkty: 205Zdobyte punkty: 1205Wymienione punkty: 1000

Wypełnienie profilu

D R P Z S U33% 0% 0% 0% 0% 0%

Polecaj i zarabiaj!

Pochwal się tym na facebook!

Na końcu każdej ankiety znajduje się przycisk Podziel się na FB. Kliknij w niego, a otrzymasz dodatkowe punkty

Dostępne badania

Data	Liczba punktów za badanie	Tytuł:
2018.06.07 Czas badania 15min	50pkt	Preferencje w Polsce
2018.06.07 Czas badania 15min	50pkt	Preferencje w Polsce

Zakończone badania

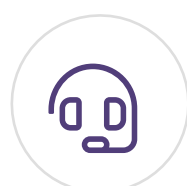
Data	Punktów	Tytuł:
2018.06.07	50pkt	Preferencje w Polsce
2018.06.07	50pkt	Preferencje w Polsce
2018.06.07	50pkt	Preferencje w Polsce

BioStat®



CATI, CAWI, CAPI research software.

Management, creation and implementation of online surveys and surveys from a single platform.



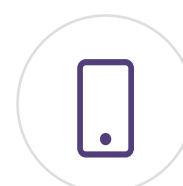
CATI

Implementation of telephone surveys, supervising the work of remote interviewers



CAWI

Reaching out to selected, even small or highly specialized groups of respondents



CAPI

Comprehensive solutions for mobile devices



BioStat®

R&D Discount

A favourable tax instrument in the hands of
BioStat®.

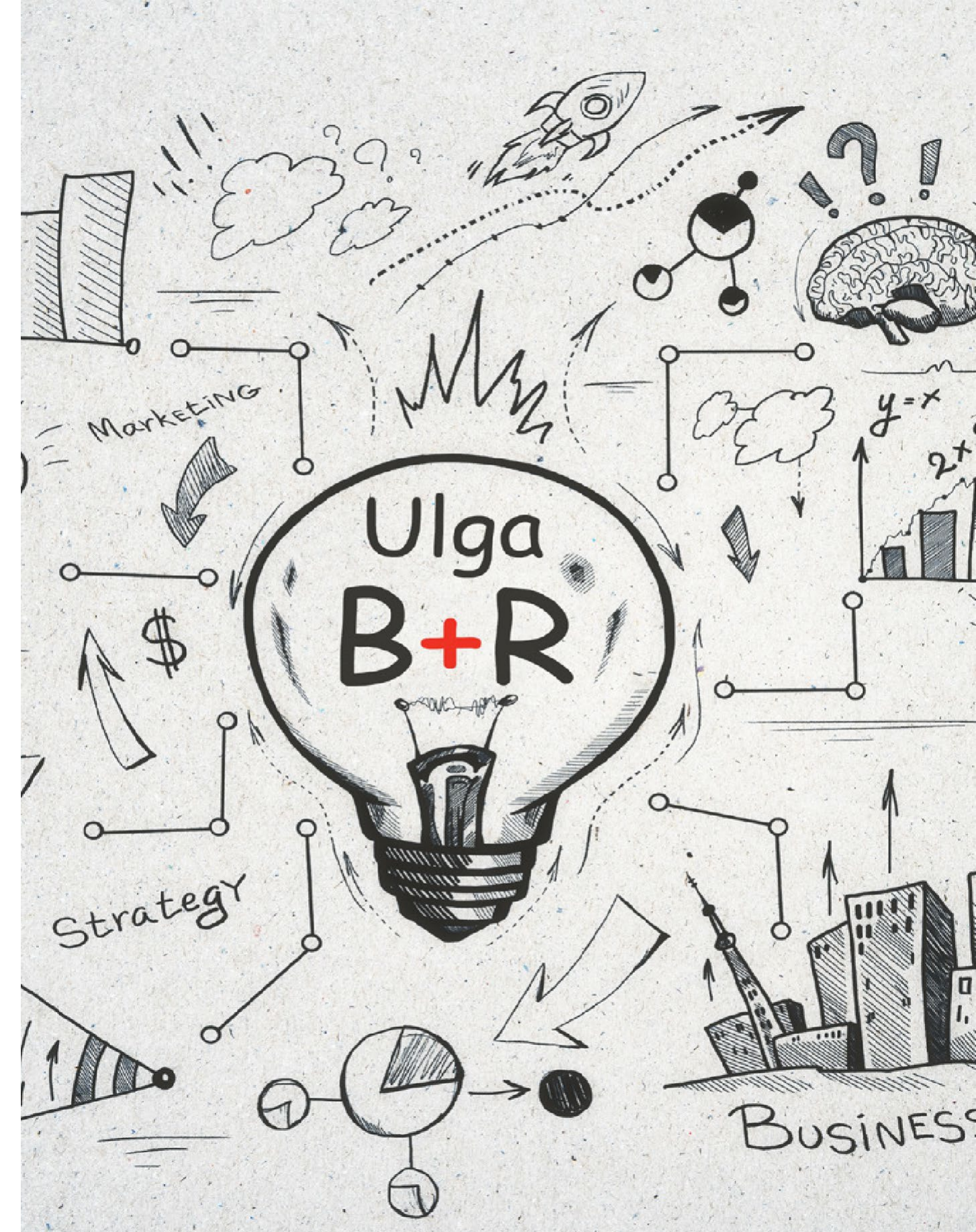
The most attractive form of support for R&D activity on the Polish market. An uncomplicated mechanism to deduct from the tax base costs incurred for R&D activities, the so-called eligible costs.

If you improve your technologies, products, services or create new ones from scratch with BioStat®, you may meet the conditions for conducting R&D activities eligible for the relief.

The condition for taking advantage of the relief is to conduct development activity (it is not required to conduct scientific research, have the status of a R&D center or cooperate with scientific entities).

Ultimately, the costs of research conducted by the BioStat® Research and Development Centre are up to **20% lower***.

BioStat® is one of the narrow group of entities that are entitled to issue an Innovation Opinion according to the standards described in the Oslo Manual (*Oslo Manual 2018. Guidelines for Collecting, Reporting and Using Data on Innovation.*)



Preparation time: about 10 days
Cost: from several to over a dozen thousand zlotys

BioStat®

Clients that trust us:





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