



# Full-Service CRO

## Clinical Research

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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.

**+20**  
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.)



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# Therapeutic areas

Projects implemented in various fields:

Oncology

Gastroenterology

Transplantology

Cardiology

Neurology

Allergology

Psychiatry

Neonatology

Diabetology

Pulmonology

Immunology

Andrology

Proctology

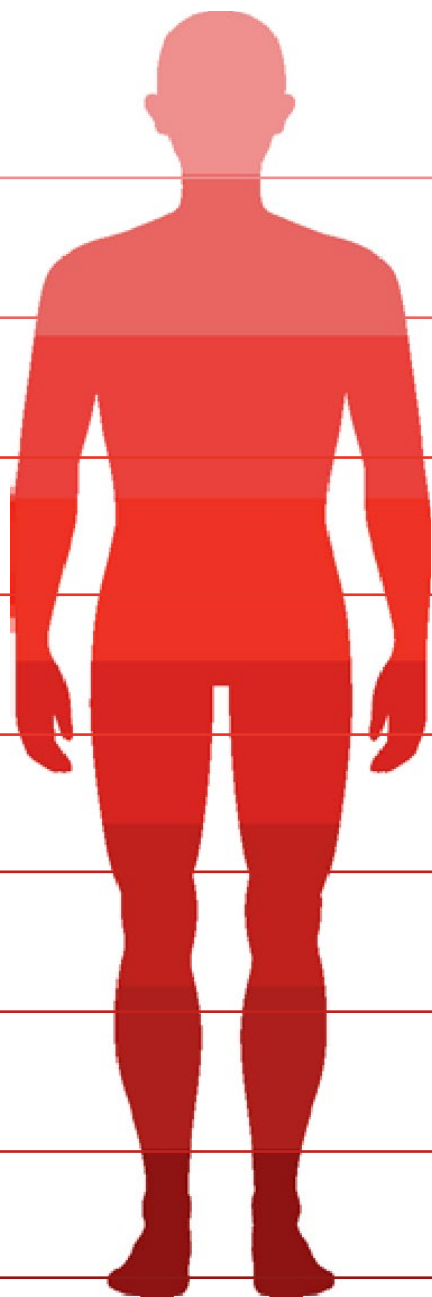
Dermatology

Ophthalmology

Rheumatology

Virology

Hematology



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# 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



# 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

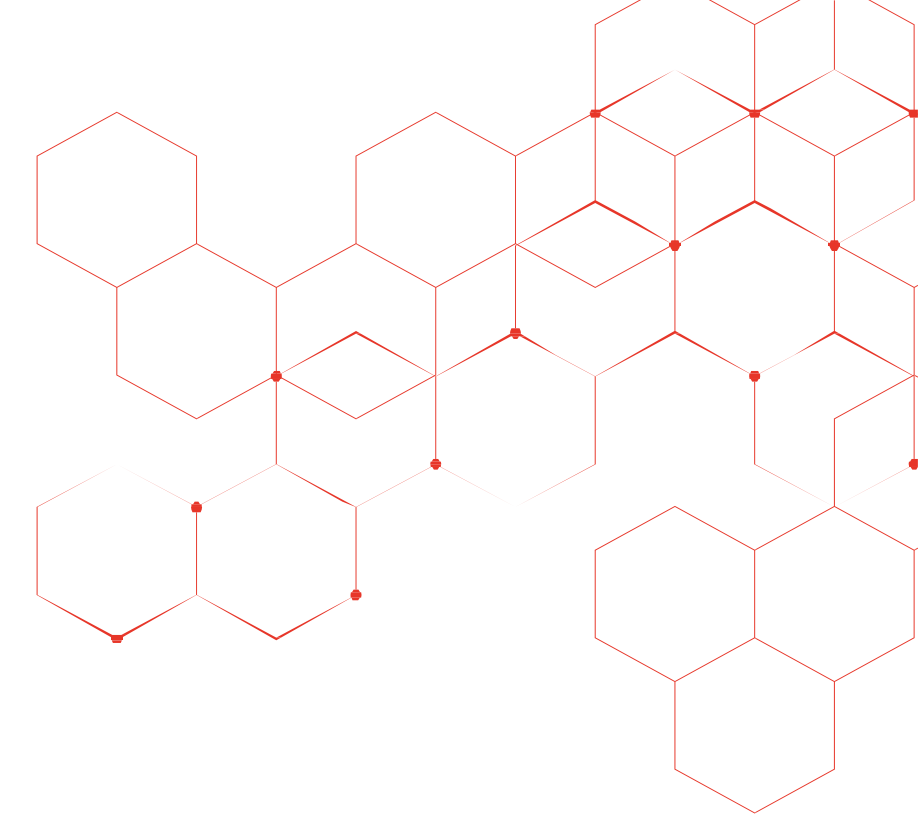
Study monitoring

Study management and supervision of study

Statistics, analysis

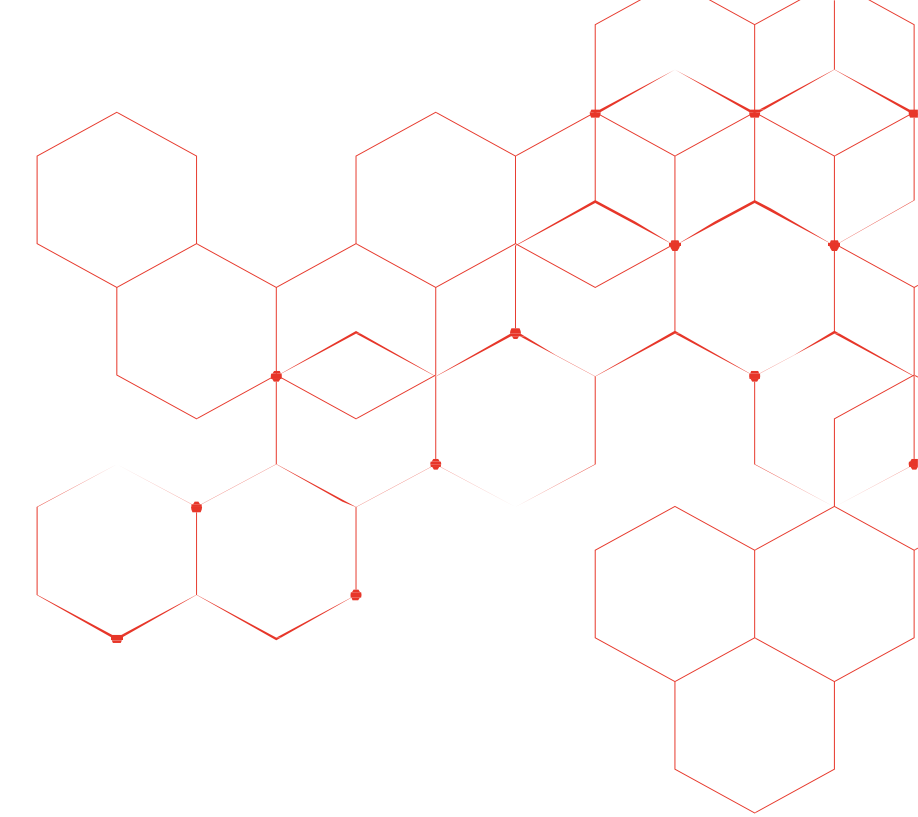
Assistance in preparing publication of study results

Counseling/consulting





# 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



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# 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



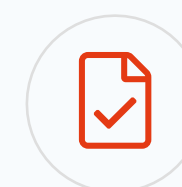
SPSS



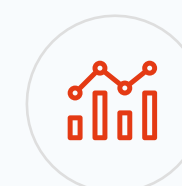
Python



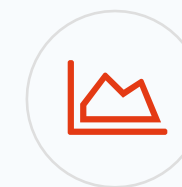
Basic descriptive statistics



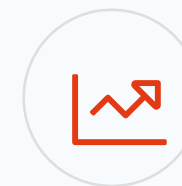
Verification of statistical hypotheses



Interdependence analysis



Multidimensional analyses

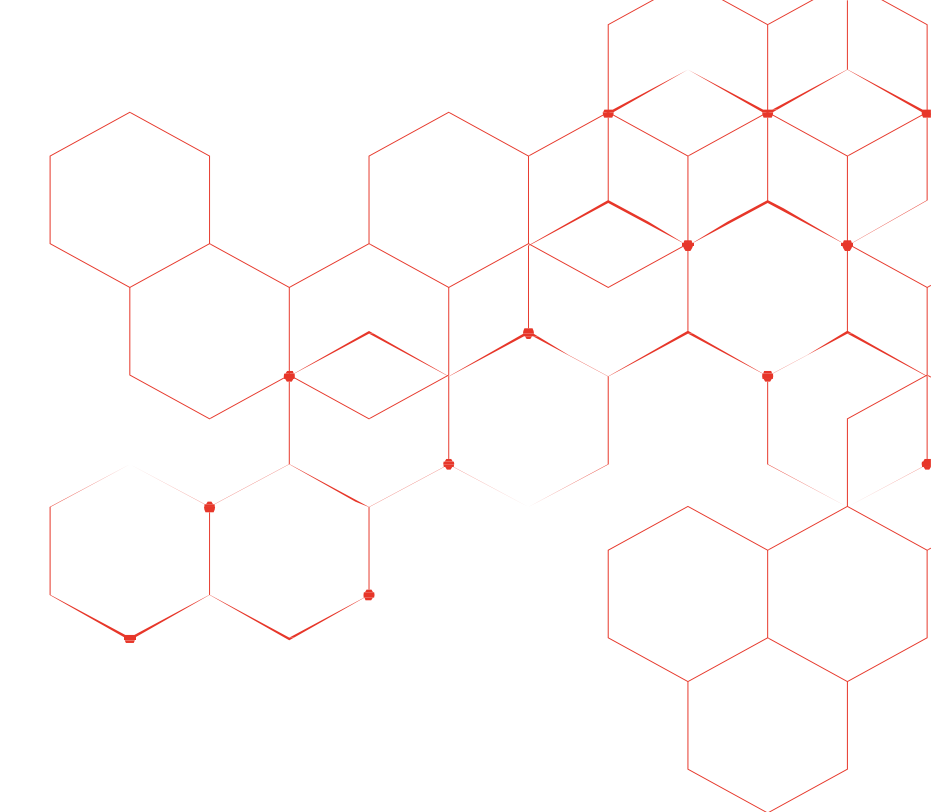


Evolutionary algorithms



# 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

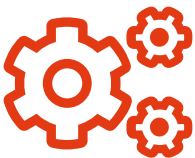
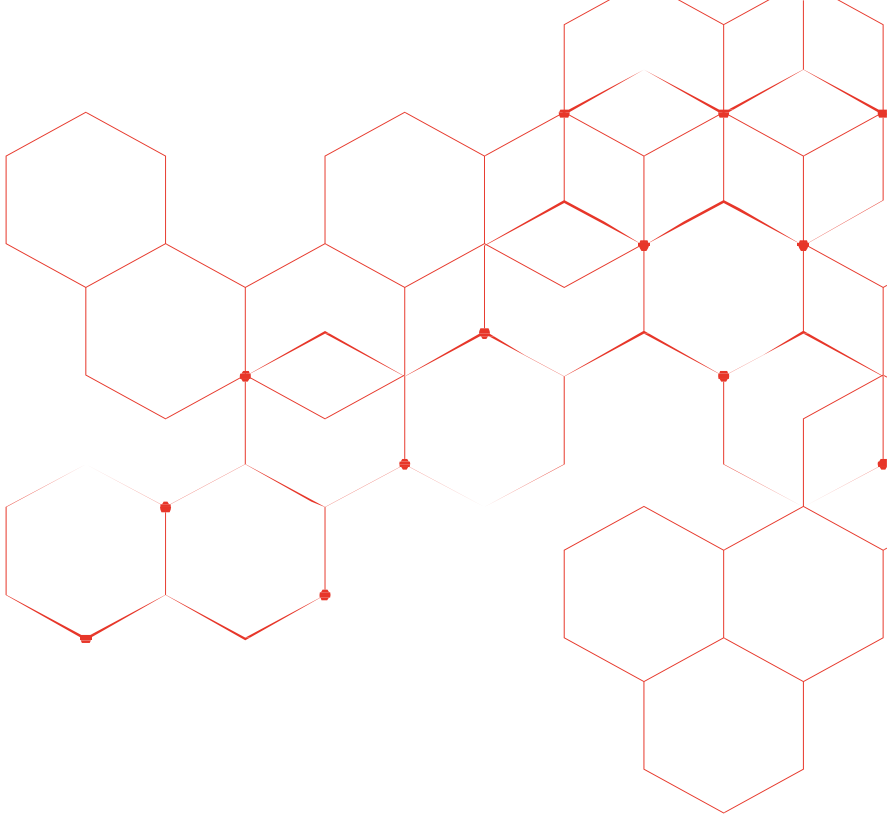
## DATA PROCESSING

- 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

# 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



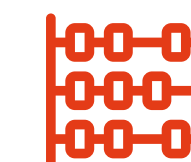
Unlimited number of  
studies



Interoperable and  
scalable platform



Integration with the  
online contracting  
system



Full validation and  
specific tests



# eCRF.biz™ functionalities

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

**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

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)



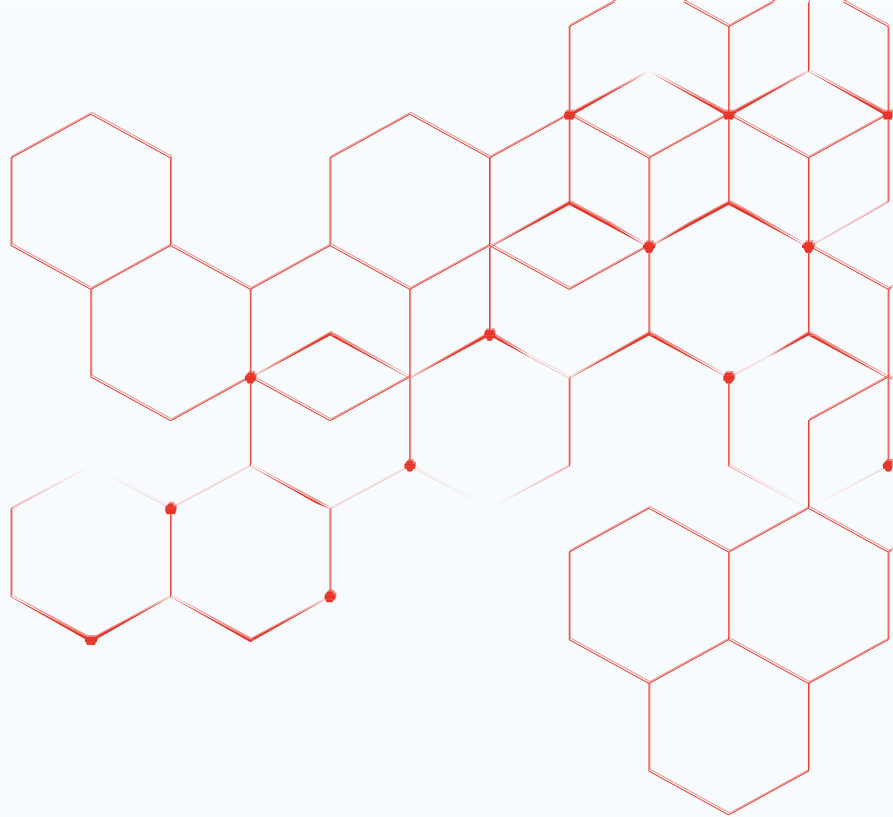
The ability to collect data at the  
site and at home



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

## 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



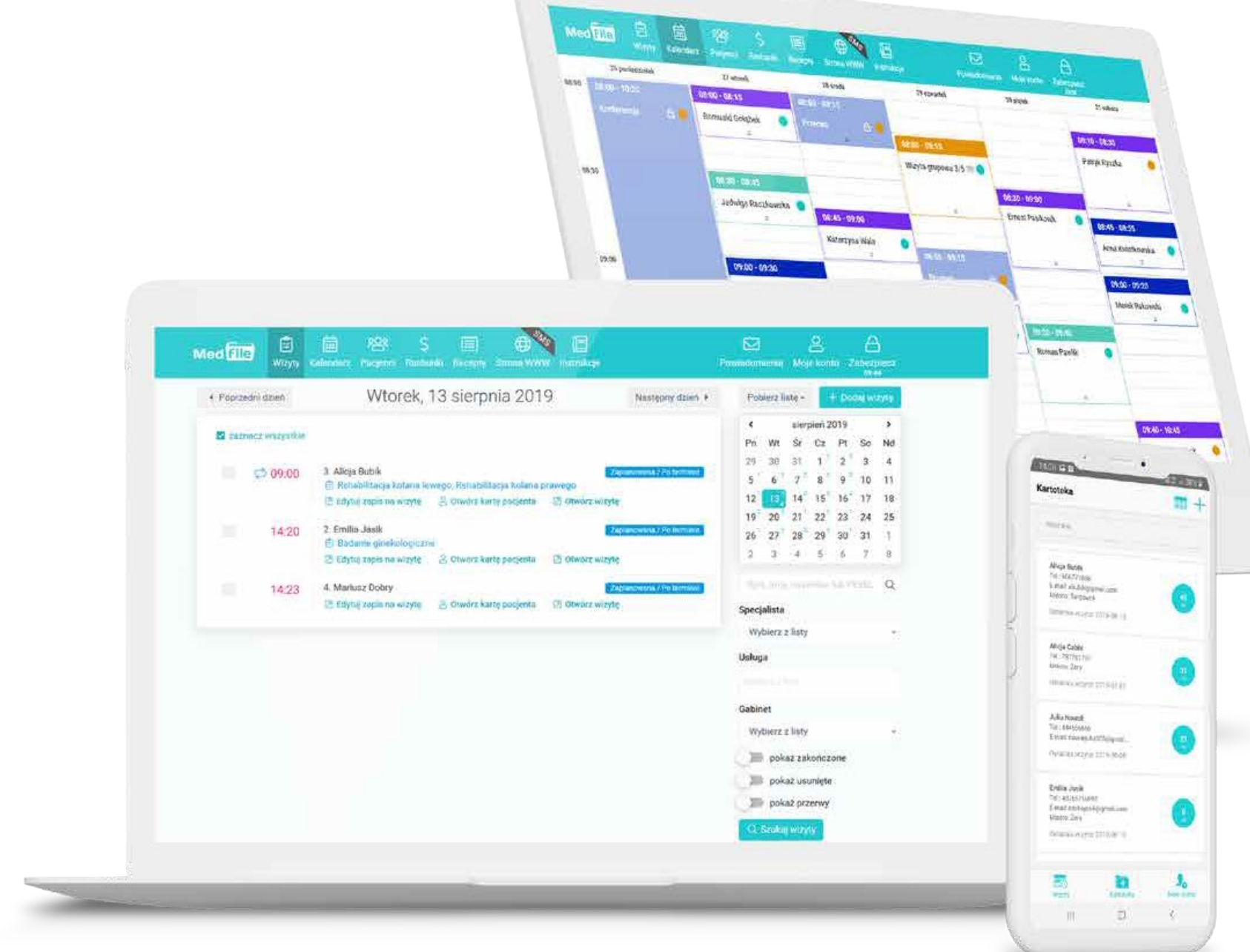
Visit card



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



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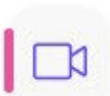
Telemedicine platform - online consultation

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.*



Wideo



Czat



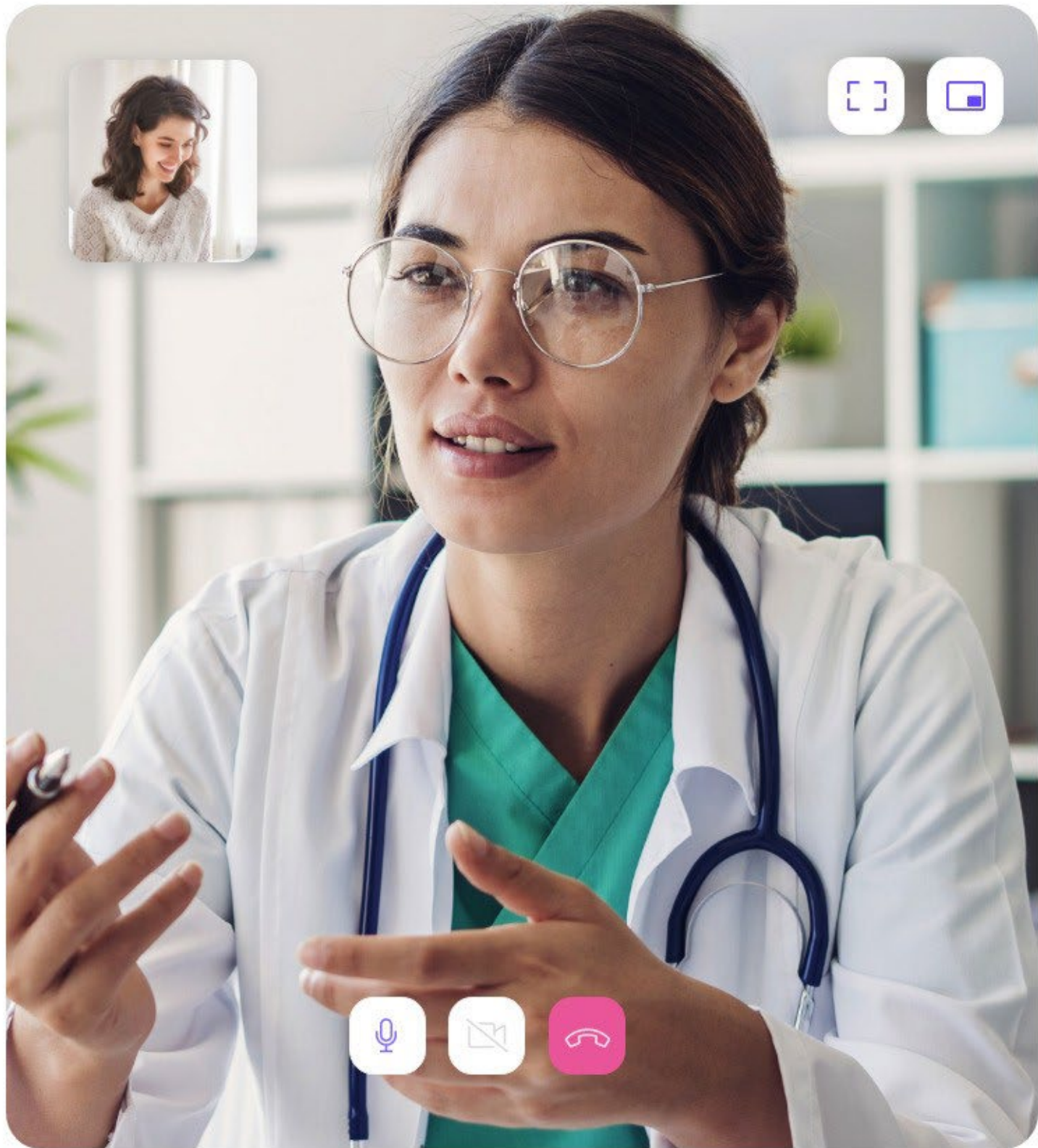
Dokumenty



Udostępnij



Pomoc



Opis

Dzień dobry, odczuwam od rana z  
sobie przed chwilą ci  
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


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[Ankieta](#)
[Baza klientów](#)
[Panel Badanie Opinii](#)
[Statystyki](#)
[Ustawienia](#)
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[Statusy](#)
[Rozszerzenia](#)
[Uprawnienia](#)
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**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 firmy

testowy

Imię\*

testowy

Ulica\*

testowy

Kod pocztowy

testowy



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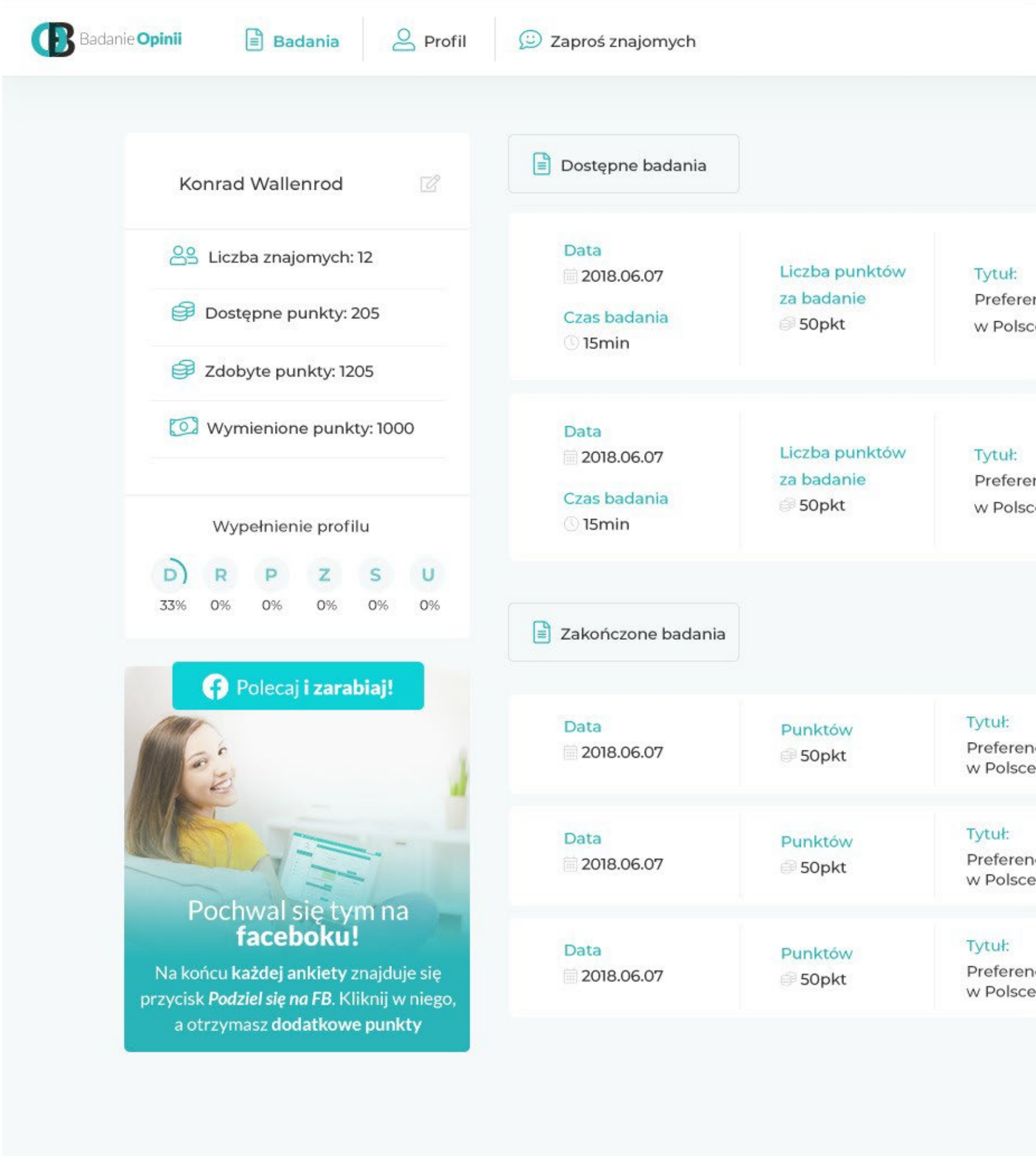
Consumer panel for surveys.

A nationwide consumer base allowing for the implementation of a wide range of market research, opinion polls and surveys, focusing on online surveys.

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

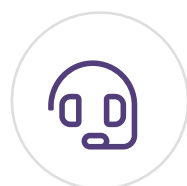


BioStat®



*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®.*

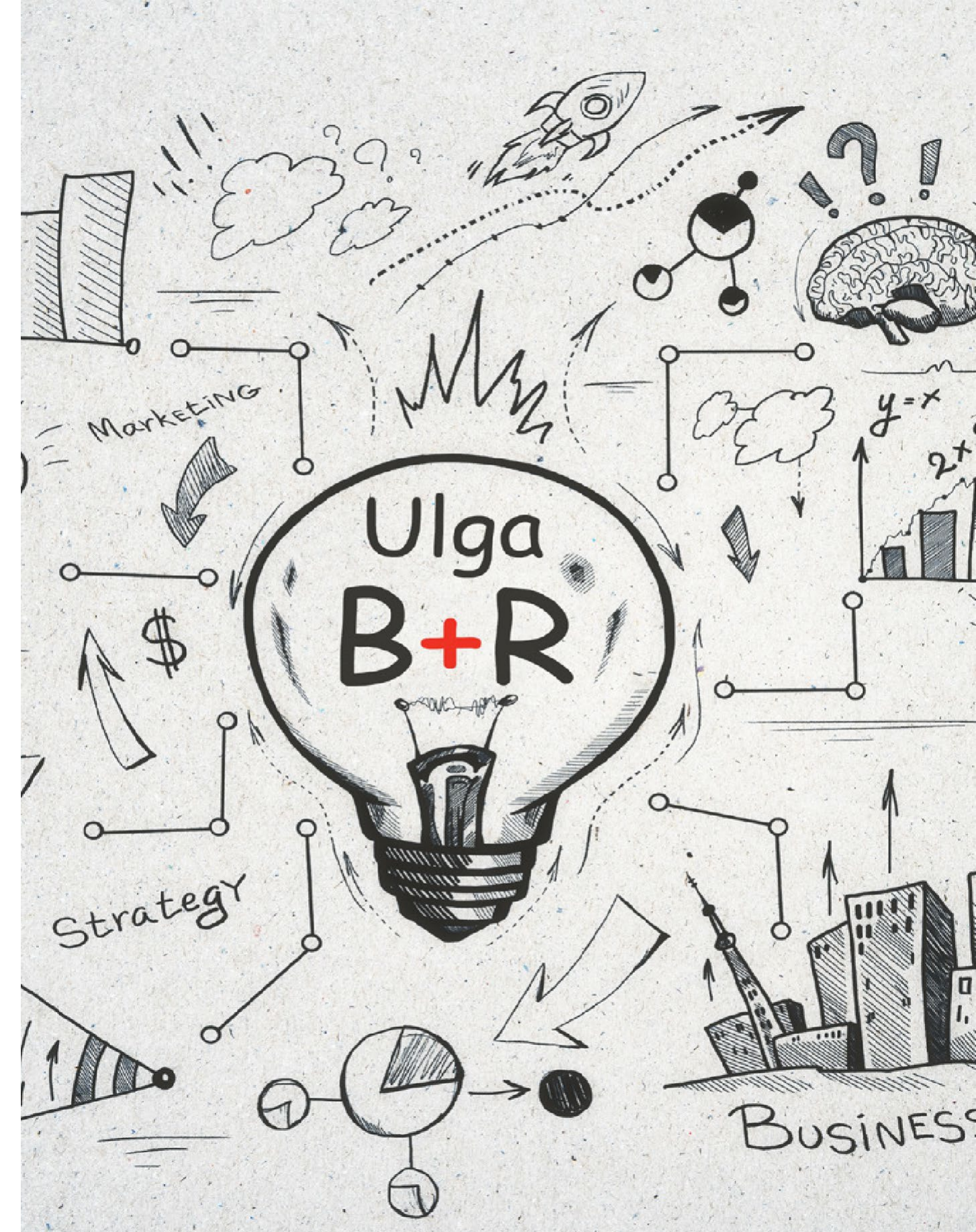
The most attractive form of support for R&D activity on the Polish market. An uncomplicated mechanism to deduct from the tax base costs incurred for R&D activities, the so-called eligible costs.

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®

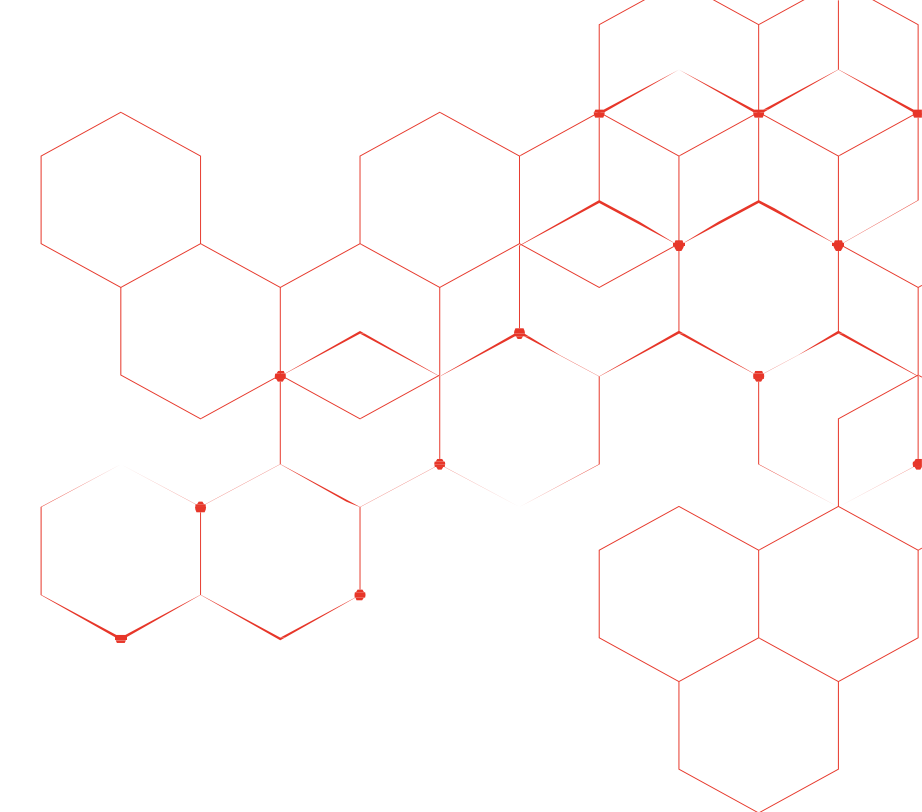
# Clients that trust us:







CENTRUM  
BADAWCZO-ROZWOJOWE



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