

Clinical Trial Software

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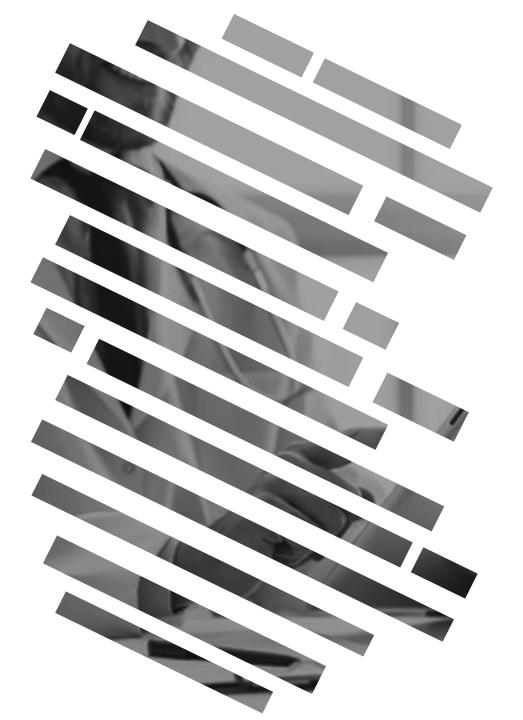


eCRF.bizTM

MODERN TECHNOLOGY IN BIG DATA SERVICE

The world is changing, and so are we.

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



eCRF.biz™ Move your research Into a digital world

The system has been created by professionalists for professionalists in accordance with FDA Title 21 CFR Part 11 standards.

Precise data management and their completeness.

IT team, statisticians, and in-house data managers.

100% Digital

Clinical trials Observational research (NIS) PASS research Medical registers PMS Study

Want to reach more? See a demo research

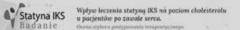
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Access

For everyone interested

Administrator Data management Medicine suppliers Doctors Alternative physicians Other medical staff Monitors Medical monitors Sponsor





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Unique Research Design

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WORK FLOW

Research design - Data gathering - Statistical analyses





work FLOW Research Design

- Statistical Analysis Plan(SAP)
- Justification for the research realisation
- Randomisation and sample size selection
- Preparing CRF
- Key Visual research

work FLOW Data Gathering

- Creating research database
- Preparing data for statistical analysis
- Data Management Plan





work FLOW Statistical **Analyses**

- Reports and transient analysis
- Final report elaboration
- Graphic layout

eCRF.biz[™] FUNCTIONS AND PROPERTIES OF THE SYSTEM 3100 SUPPLET DATES

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STUDIES

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EL TRUL PROGRESS

PATIENTS FILE

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research type and forms of access cafeteria – widgets (drag&drop) comments audit trail data queries rules and conditions creator data validation - seals notifications 120 120 2.00 reports randomisation, drug management online contracts signing security remote access data backup

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Research types and forms of access

The research realisation requires varioues forms of access and data gathering processes:

Anonymous research

The access is given to anyone who has received a link only to the questionnaires.

One-off codes The access is granted after providing

special access code.

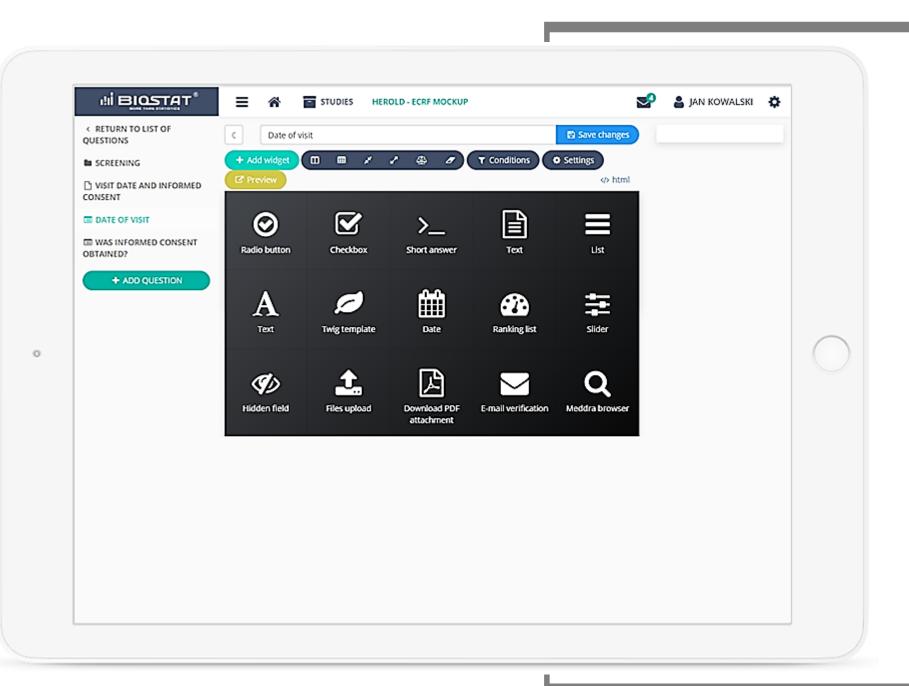
Individual login and passwords

Access to the questionnaire and user interface

Possibility to fill in various questionnaires based on unique e-mail address and user's password in eCRF applications.

Access to the questionnaires is realised by "users/doctors" module.

	😑 🏫 🖬 Studies
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	Screening
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Cafeteria widgets (drag&drop)

Field types

- single-choice option field (divided into groups within one question)
- multiple-choice option (divided into groups)
- short answer (single-line text field)
- open questions (long, multiple-line answer)

Cafeteria – widgets (drag&drop) List of choice Informative text Twig template Date (date section) Ranking list Slider Hidden field E-mail verification Meddra browser Relation between sites

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Autosuggestion field for linking selected repeatable sites with the other ones – in order to, e.g. Determin the relationship between the values in a questionnaire with adverse events.

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FUNCTIONS AND PROPERTIES OF THE SYSTEM

Comments

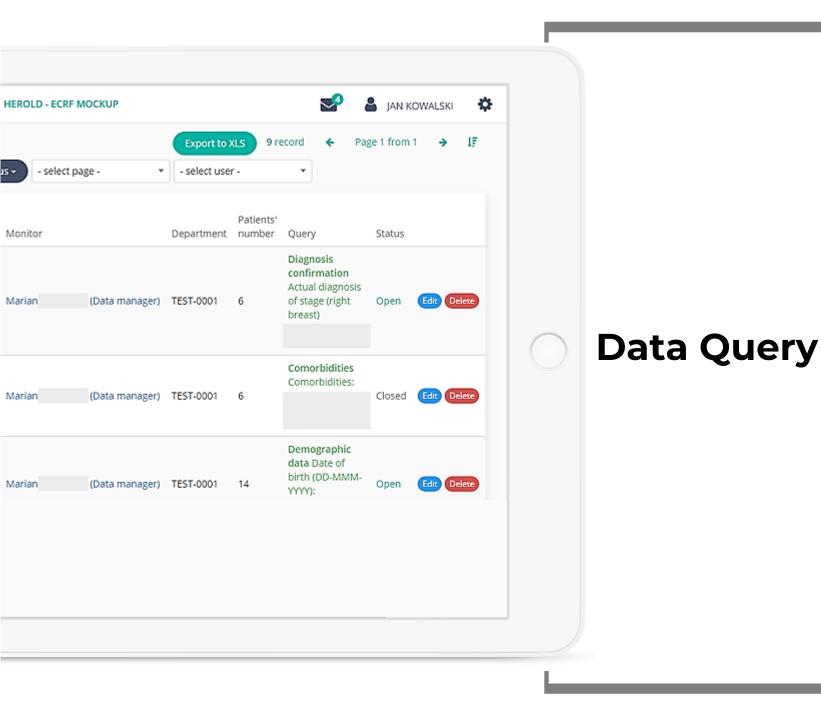
Possibility of editing and making remarks to a questionnaire; the function is active only in the research design phase.

Audit trail

Every questionnaire change done by users is recorded.

Audit trail overview is possible for every question with a division into exact time and author of the change.

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Query processing

Monitors can add queries to every question and site in a questionnaires.

Notifying doctor/monitor about a new query

Doctors receive automatic e-mail notification about new queries for Patients.

Responses to queries

The monitor is notified once the doctor gives an answer.

Site/query seals breaking

After every patient's data modification due to the processed query, the verification seals are broken, so the monitors have to check the modifed sites again.

Rules and conditions creator

Creator allows to make conditions for selected fields from the whole questionnaires.

There can be more than one condition and they can be based on various logica criteria (and/or).

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Every field of the following type:

- list of choice
- radio
- checkbox
- text field
- date field
- ranking field
- slider

The fields can be included in any conditions creator available in eCRF.

III BIOSTAT	Conditions	
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Data Validations - seals

FUNCTIONS AND PROPERTIES OF THE SYSTEM

Monitors have the possibility to sign every question, site and and questionnaire visits; digital signature and doctor's approval result in special sign in the shape of a round seal.

Seals breaking

After query is added to any question, the doctor is informed about possible error occurrence in the questionnaire; he/she is given then a temporary access to edit the priorly closed site; if the change is entered to the database, then all seals for particular question, site and visits to which the change refers are broken; monitors have to check the visit history and sign the document if possible.

Multi-personal seal

All data in the system can be signed by an unlimited number of people.

Notifications

Adverse events, superior values provided in the cafeteria, or patient's status change often require to urgently notify selected group of people or monitors.

Settings

E-mail and status (active/inactive) come under configuration, as well as the type:

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 notification sent to selected group of addressees

 notifications sent only to the author of the changes in the questionnaire (e.g. Doctor)

 PDF file generated from the questionnaire content – downloaded by the user while filling it up

 a notification with a contract to sign – only to the author

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Randomisation, drug management

FUNCTIONS AND PROPERTIES OF THE SYSTEM

Medicine and phials database divided into branches and groups; medicines are blinded, randomisation automatically selects the patients in given proportions; in order to assign patients to the randomisation module, one has to set up the input conditions in creator known from conditions on sites and questions.

Medicines

Medicine database is an advanced forwarding mechanism which aims at medicines management from the moment of shipping from the warehouse to reaching the end-centre; audit trail of the medicine as well as all actions are recorded.

Blinding

The information referring to the type of medication given to particular patients is provided to all parties in the research only in the final report and after closing the database and medicines unblinding.

Reports

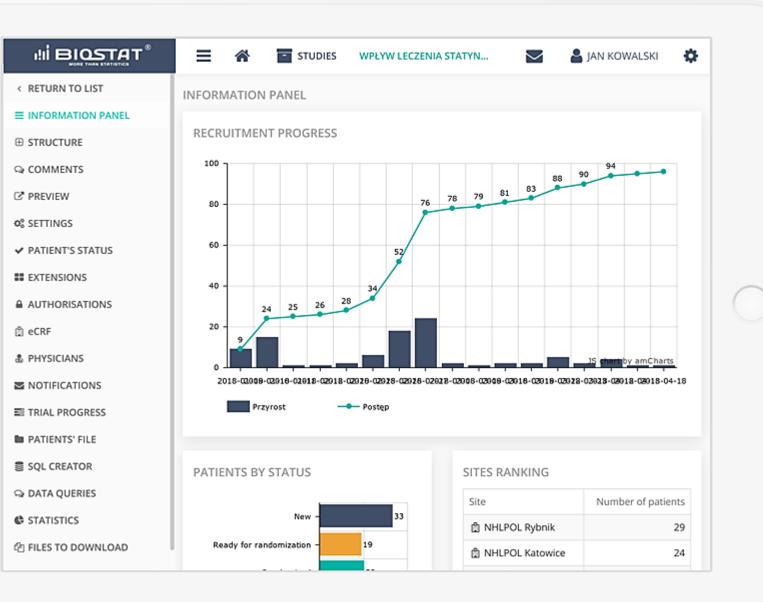
Reports on the basis of visits and selected questions (by using TWIG system for data generation).

Reports on the basis of SQL (administrator).

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Reports on the basis of "R" environment with the use of Latex and other libraries.

Reports on the basis of the sample analysis.



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Online contract signing (documentation)

FUNCTIONS AND PROPERTIES OF THE SYSTEM

Thanks to the electronically signed documents, we limit the amount of printing; it also allows to speed the contracting process up, as well as improve settling accounts with researchers and sign possible annexe – in case of research prolongation.

Positive opinion from DZP law agency.

Access code

Registration form

Receiving contracts on Emails

Security

System security

- encrypted connection
- SQL Injection attack protection
- verification of any data transmitted into the application
- use of transactions in order to keep data integrity
- registering users requesting for the access to the system
- access only for authorized users.
- the access is granted only to users directly related to the projects realised by eCRF





Security

FUNCTIONS AND PROPERTIES OF THE SYSTEM

Physical server security

- limited access to devices and servers
- every server room is connected to two independent internet and electrical connections
- data backup is processed in real-time
- switching to a spare server is processed immediately by IP Failover

Security

Logical security

- multilevel firewall systems, detection and active intruders blocking system (IDS/IPS), logical network division (VLAN)
- antivirus systems
- every user has a unique ID and password
- unauthorized login attempts are registered
- ongoing monitoring and software updates





Remote access

FUNCTIONS AND PROPERTIES OF THE SYSTEM

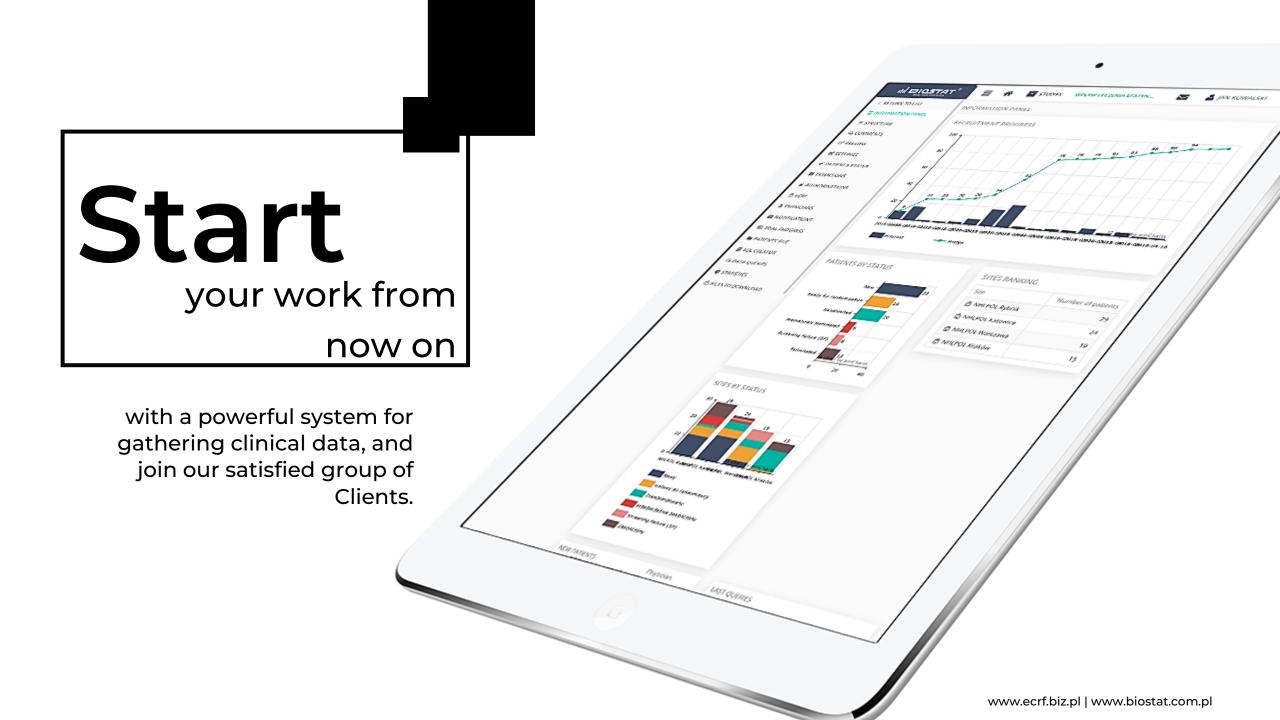
You can enter the system from any place via Internet web browser.

Data backup

Data backup is processed in realtime.

Switching to a spare server is processed immediately by IP Failover.





Our Clients eCRF.biz™

"The level of eCRFTM implementation in the BioStat® system meets the highest European standards and can be a showcase of the possibilities of Polish companies operating in a difficult and extremely competitive field. The quality of the IT solutions provided by BioStat® outperforms most alternative eCRFTM systems in terms of functionality and security. " MILTON ESSEX S.A.





"Created by BioStat® Sp. z o. o. system is transparent and easy to use. Professional technical support of the eCRF[™] system means that any changes are introduced immediately, which does not cause interference in the course of the study. " Mabion

> "BioStat® is very flexible in planning and proposing solutions, which is highly valued in the present times. I consider BioStat® to be a trustworthy and recommending service provider in which it is worth entering into cooperation. " EGIS



































OF WARSAW

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