



eCRF.biz™
electronic Case Report Form

Clinical Trial Software



eCRF.biz™

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 professionals for professionals 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



Access

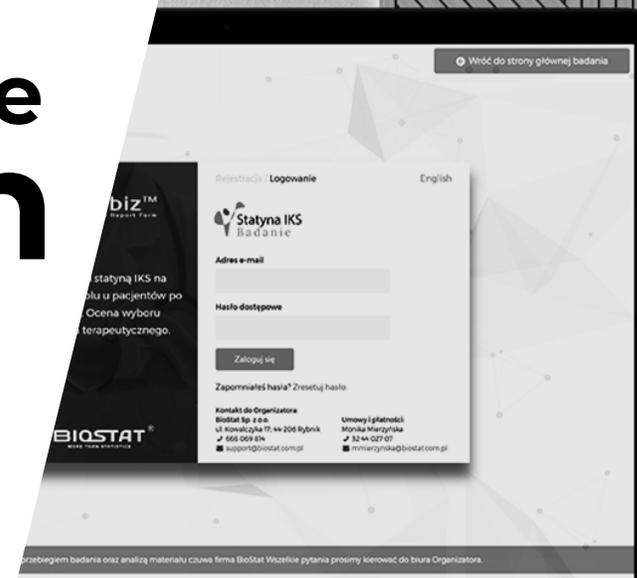
For everyone interested

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



eCRF.biz™
electronic Case Report Form

Unique Research Design





WORKFLOW

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

FUNCTIONS AND PROPERTIES OF THE SYSTEM

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

| Date | Patient | Physician | Status | Department |
|---------------------|--------------|--------------------|-----------|------------|
| 2018-05-17 13:15:58 | BIOSTAT.02 | Plechaczek Mateusz | TEST-0001 | BIOSTAT |
| 2018-05-17 13:15:52 | BIOSTAT.01 | Lekarz Testowy | TEST-0001 | BIOSTAT |
| 2018-05-11 12:51:40 | TEST-0001-16 | Lekarz Testowy | TEST-0001 | BIOSTAT |
| 2018-05-02 11:26:22 | TEST-0001-15 | Lekarz Testowy | TEST-0001 | BIOSTAT |
| 2018-04-30 16:14:26 | TEST-0001-14 | Lekarz Testowy | TEST-0001 | BIOSTAT |
| 2018-04-26 14:49:05 | TEST-0001-13 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-04-05 12:01:37 | TEST-0001-12 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-04-05 08:36:33 | TEST-0001-11 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-04-04 14:34:53 | TEST-0001-10 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-04-04 12:25:57 | TEST-0001-09 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-04-04 11:23:21 | TEST-0001-08 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-04-04 09:40:12 | TEST-0001-07 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-04-04 09:36:11 | TEST-0001-06 | Lekarz Testowy | TEST-0001 | BIOSTAT |
| 2018-04-04 09:36:11 | TEST-0001-05 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-03-26 17:50:40 | TEST-0001-04 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-03-26 17:50:40 | TEST-0001-03 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-03-26 17:50:40 | TEST-0001-02 | Natalia Koba | TEST-0001 | BIOSTAT |
| 2018-03-26 17:50:40 | TEST-0001-01 | Lekarz Testowy | TEST-0001 | BIOSTAT |

FUNCTIONS AND PROPERTIES OF THE SYSTEM

Research types and forms of access

The research realisation requires various 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

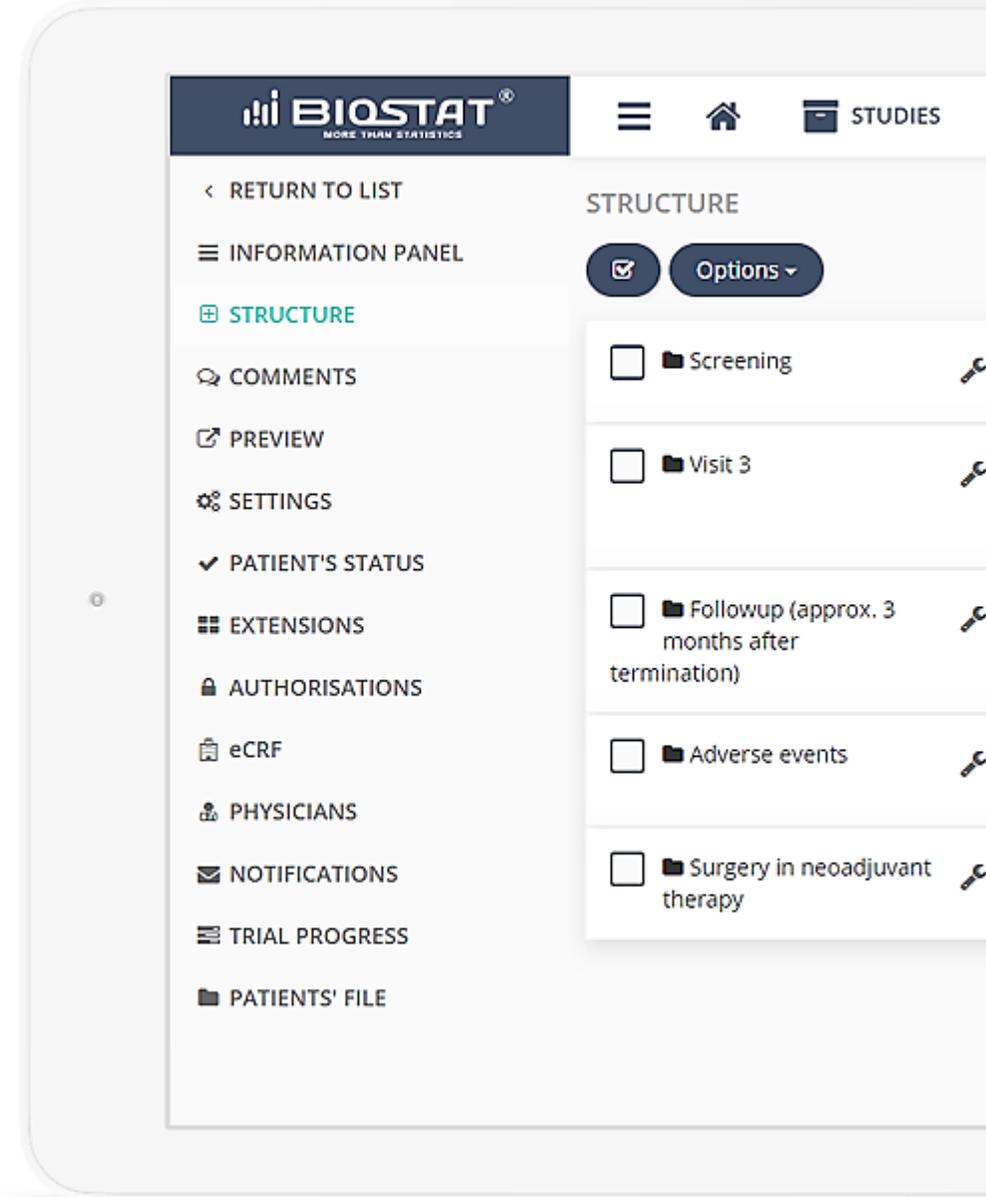
The access is granted after providing special access code.

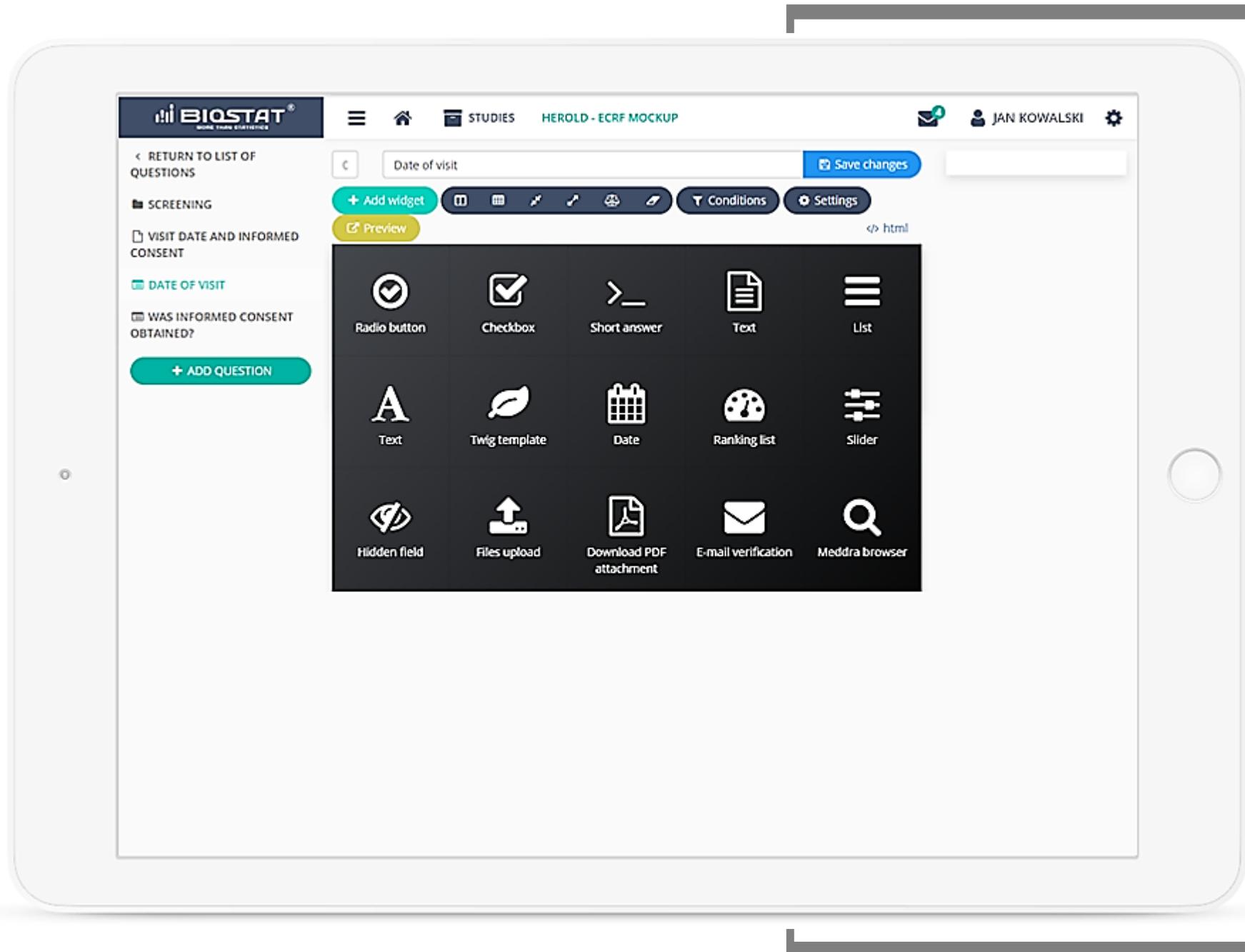
Individual login and passwords

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.





FUNCTIONS AND PROPERTIES OF THE SYSTEM

Cafeteria - widgets (drag&drop)

Field types

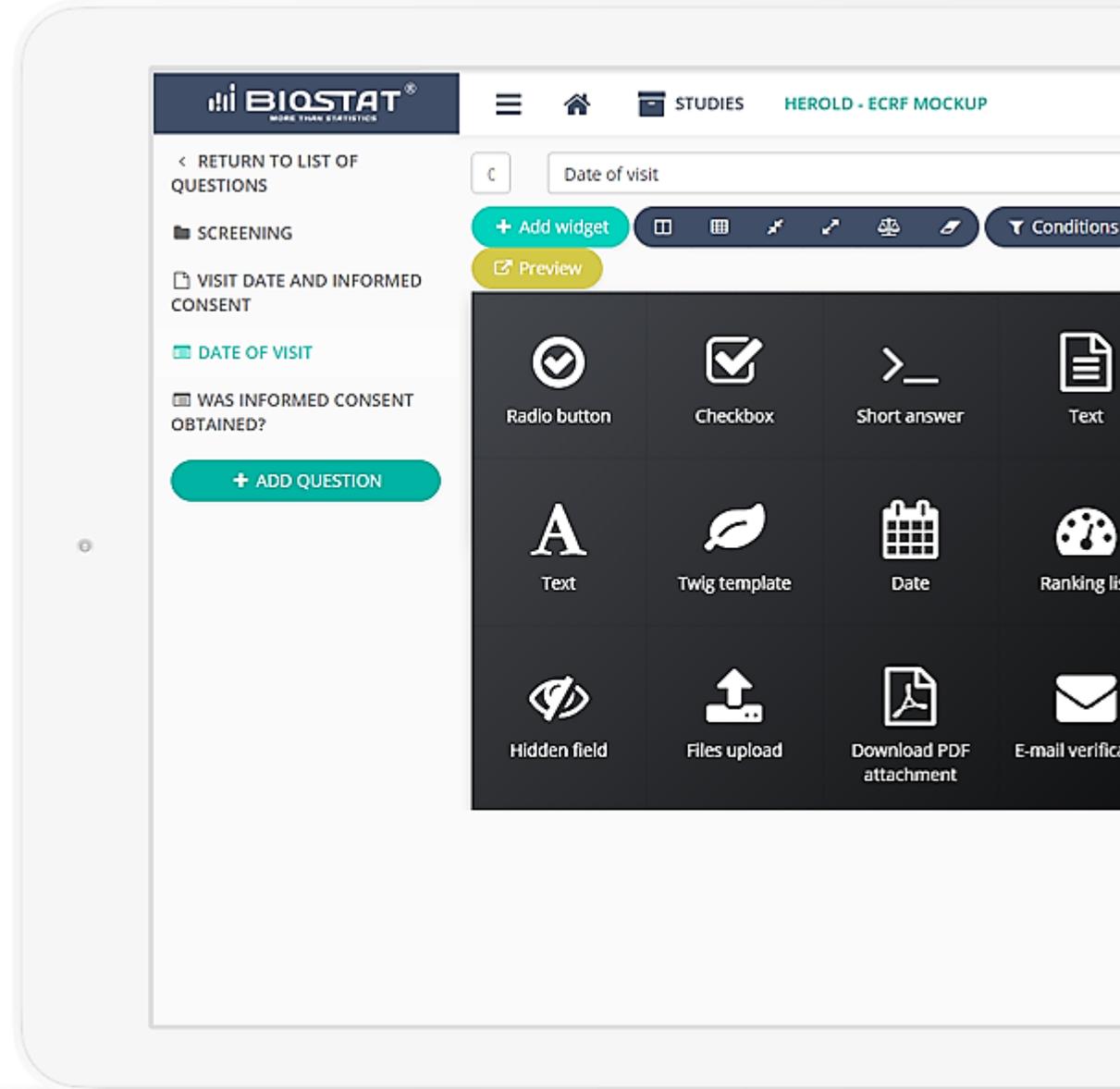
- single-choice option field (divided into groups within one question)
- multiple-choice option (divided into groups)
- short answer (single-line text field)
- open questions (long, multiple-line answer)

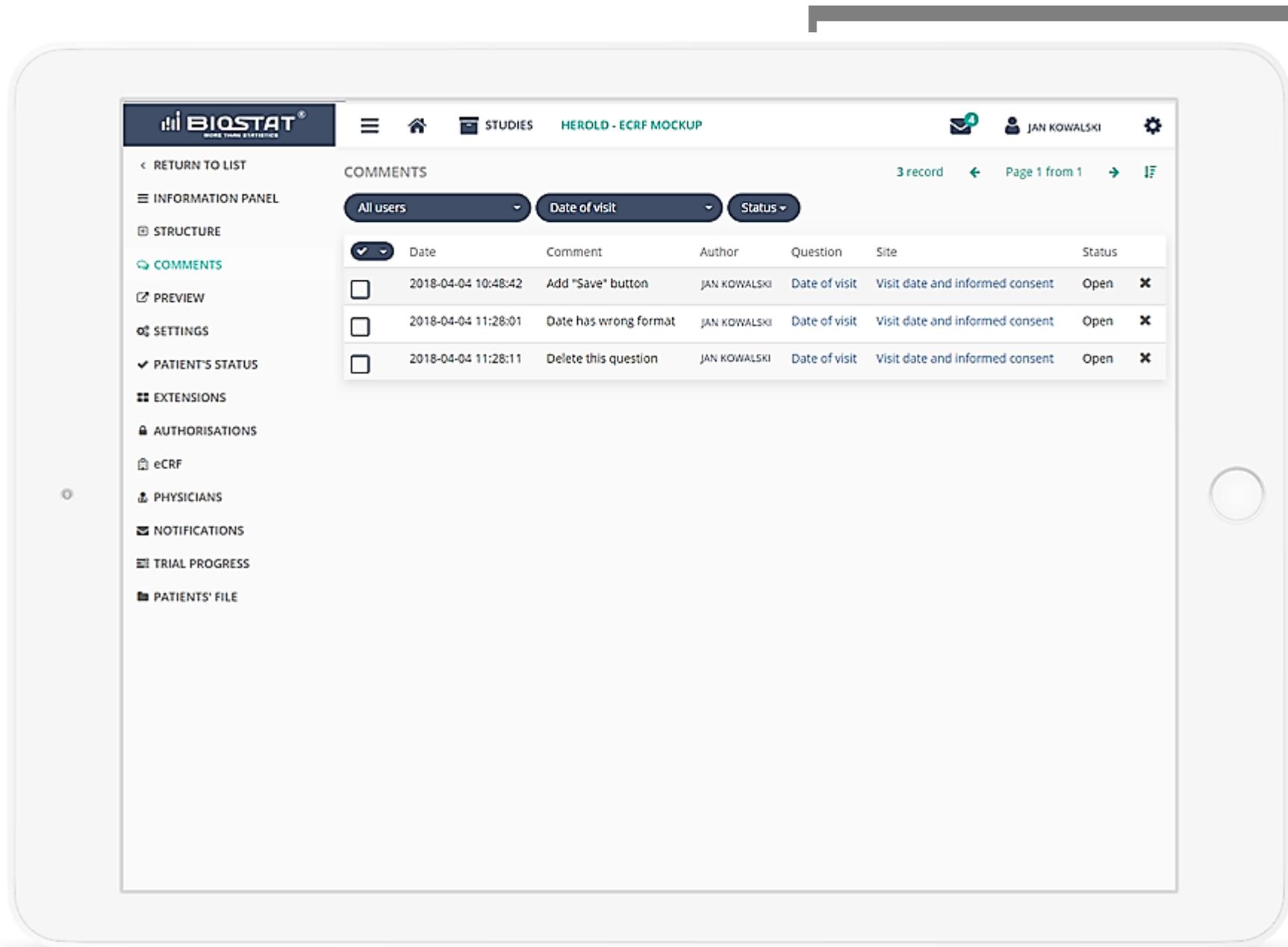
FUNCTIONS AND PROPERTIES OF THE SYSTEM

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

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





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.

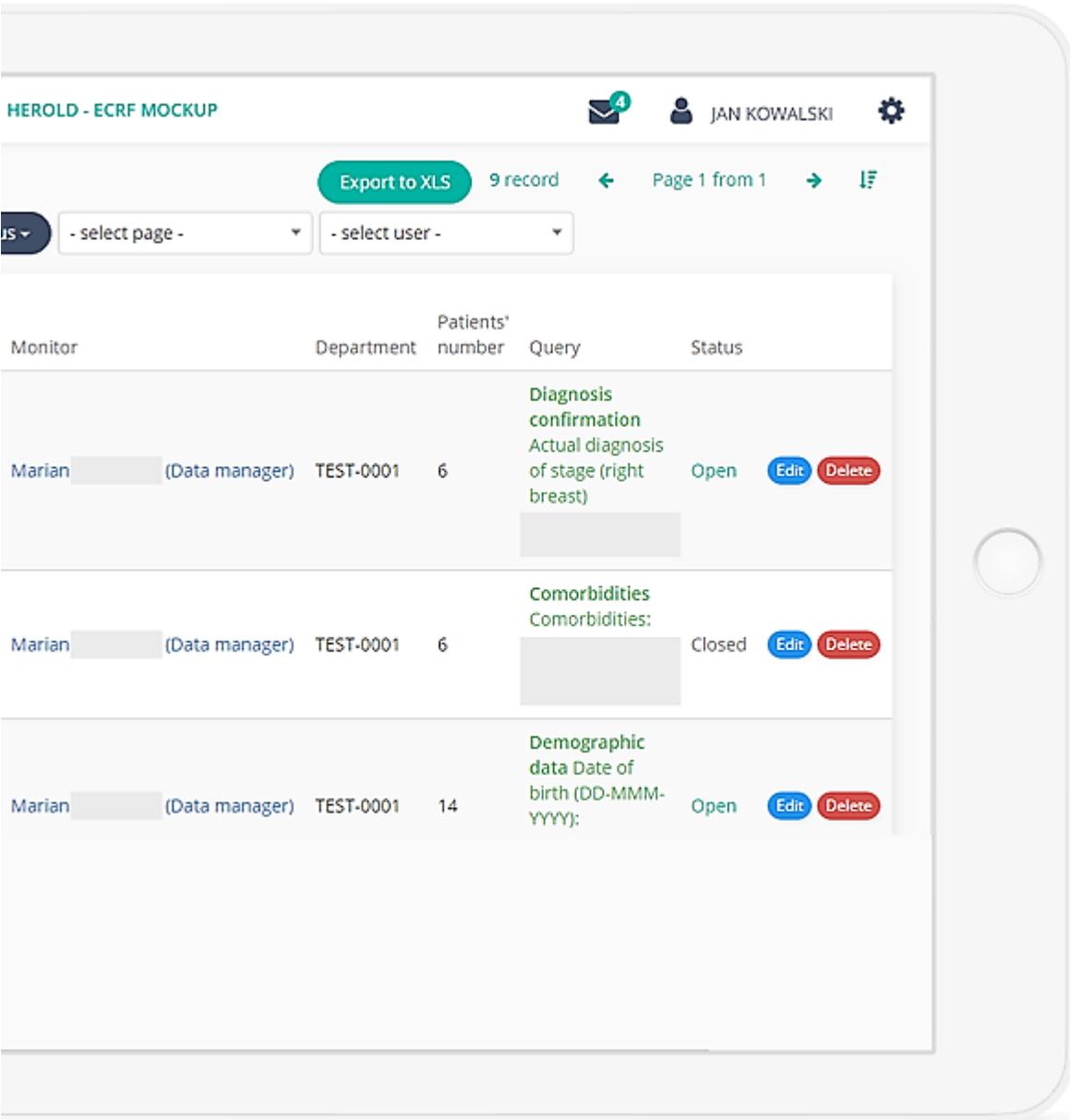
FUNCTIONS AND PROPERTIES OF THE SYSTEM

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.

| Date | Patient | Physician | Department | Status | Screening |
|---------------------|--------------|-----------|------------|-------------------------------|-----------|
| 2018-05-17 13:15:58 | BIOSTAT-02 | Mateusz | BIOSTAT | - brak - | |
| 2018-05-17 13:15:52 | BIOSTAT-01 | Mateusz | BIOSTAT | - brak - | |
| 2018-05-11 12:51:49 | TEST-0001-16 | Natalia | TEST-0001 | ICF signed | 11-J |
| 2018-05-02 11:26:22 | TEST-0001-15 | Natalia | TEST-0001 | anti-HER2 therapy not planned | 17-I |
| 2018-04-30 16:14:26 | TEST-0001-14 | Natalia | TEST-0001 | Visit 1 completed | 07-J |
| 2018-04-26 14:49:05 | TEST-0001-13 | Natalia | TEST-0001 | Screening completed | 01-J |
| 2018-04-05 12:01:37 | TEST-0001-12 | Natalia | TEST-0001 | Screening completed | 05-J |
| 2018-04-05 08:36:33 | TEST-0001-11 | Natalia | TEST-0001 | Screening completed | 05-J |
| 2018-04-04 14:34:53 | TEST-0001-10 | Natalia | TEST-0001 | Visit 2 completed | 01-I |
| 2018-04-04 12:25:57 | TEST-0001-09 | Natalia | TEST-0001 | Visit 1 completed | 01-J |
| 2018-04-04 11:23:21 | TEST-0001-08 | Natalia | TEST-0001 | Visit 1 completed | 17-I |
| 2018-04-04 09:40:12 | TEST-0001-07 | Natalia | TEST-0001 | Screening completed | 04-J |
| 2018-04-04 09:36:11 | TEST-0001-06 | Natalia | TEST-0001 | Visit 2 completed | 10-J |
| 2018-03-26 17:50:40 | TEST-0001-05 | Natalia | TEST-0001 | ICF signed | 02-J |
| 2018-04-04 11:23:21 | TEST-0001-08 | Natalia | TEST-0001 | Visit 1 completed | 17-I |
| 2018-04-04 09:40:12 | TEST-0001-07 | Natalia | TEST-0001 | Screening completed | 04-J |
| 2018-04-04 09:36:11 | TEST-0001-06 | Natalia | TEST-0001 | Visit 2 completed | 10-J |
| 2018-03-26 17:50:40 | TEST-0001-05 | Natalia | TEST-0001 | ICF signed | 02-J |
| 2018-04-04 11:23:21 | TEST-0001-08 | Natalia | TEST-0001 | Visit 1 completed | 17-I |
| 2018-04-04 09:40:12 | TEST-0001-07 | Natalia | TEST-0001 | Screening completed | 04-J |
| 2018-04-04 09:36:11 | TEST-0001-06 | Natalia | TEST-0001 | Visit 2 completed | 10-J |
| 2018-03-26 17:50:40 | TEST-0001-05 | Natalia | TEST-0001 | ICF signed | 02-J |



Data Query

FUNCTIONS AND PROPERTIES OF THE SYSTEM

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 modified sites again.

FUNCTIONS AND PROPERTIES OF THE SYSTEM

Rules and conditions creator

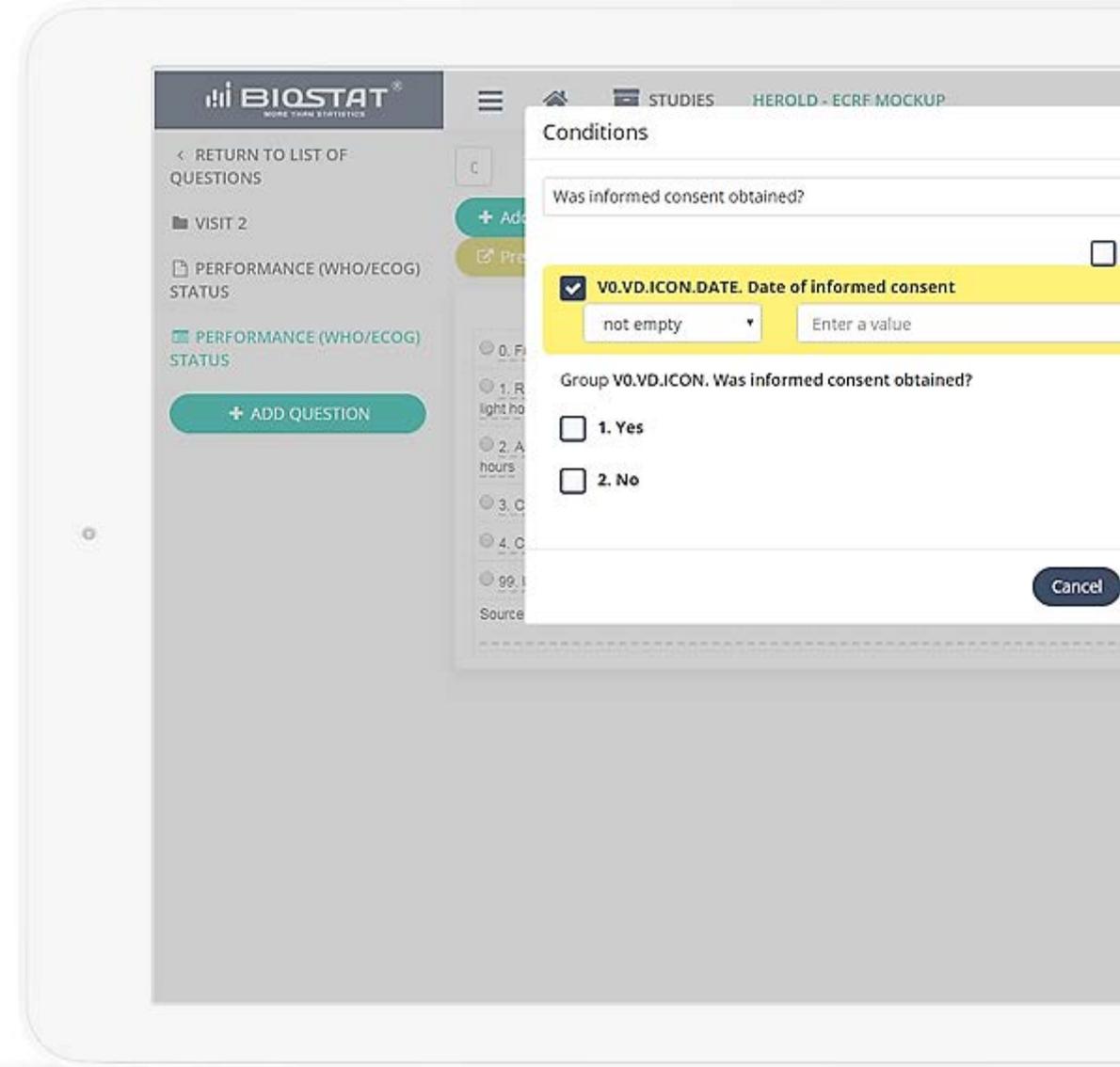
Creator allows to make conditions for selected fields from the whole questionnaires.

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

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.





18 record ← Page 1 from 1 → Export

| Patient | Status | Screening | Visit 1 | Visit 2 |
|-----------------|---------------------|----------------|---------------|---------------|
| 52 BIOSTAT-01 | - brak - | 🔒 | | |
| 58 BIOSTAT-02 | - brak - | 🔒 | | |
| 50 TEST-0001-01 | ICF not signed | 🔒 20-Feb-2018 | 🔒 | 🔒 |
| 11 TEST-0001-02 | ICF signed | 🔒 09-Jan-2018 | 🔒 08-02-2018 | 🔒 |
| 09 TEST-0001-03 | Screening completed | 🔒 23-Mar-2018 | 🔒 02-Mar-2018 | 🔒 |
| 37 TEST-0001-04 | Visit 2 completed | 🔒 05-Mar-2018 | 🔒 05-Mar-2018 | 🔒 05-Mar-2018 |
| 40 TEST-0001-05 | ICF signed | 🔒 02-Jan-2018 | 🔒 | 🔒 |
| 11 TEST-0001-06 | Visit 2 completed | 🔒 10-Apr-1895 | 🔒 04-Apr-2018 | 🔒 04-Apr-2018 |
| 12 TEST-0001-07 | Screening completed | 🔒 04-Apr-2018 | 🔒 04-Apr-2018 | 🔒 |
| 21 TEST-0001-08 | Visit 1 completed | 🔒🟢 17-May-2017 | 🔒 04-Apr-2018 | 🔒 |
| 57 TEST-0001-09 | Visit 1 completed | 🔒 01-Apr-2015 | 🔒 04-Apr-2018 | 🔒 |
| 53 TEST-0001-10 | Visit 2 completed | 🔒🟢 01-Mar-2017 | 🔒 15-Mar-2017 | 🔒 04-Apr-2018 |
| 33 TEST-0001-11 | Screening completed | 🔒 05-Apr-2018 | 🔒 05-Apr-2018 | 🔒 |
| 37 TEST-0001-12 | Screening completed | 🔒 05-Apr-2018 | 🔒 | 🔒 |
| 21 TEST-0001-08 | Visit 1 completed | 🔒🟢 17-May-2017 | 🔒 04-Apr-2018 | 🔒 |
| 57 TEST-0001-09 | Visit 1 completed | 🔒 01-Apr-2015 | 🔒 04-Apr-2018 | 🔒 |
| 53 TEST-0001-10 | Visit 2 completed | 🔒🟢 01-Mar-2017 | 🔒 15-Mar-2017 | 🔒 04-Apr-2018 |
| 33 TEST-0001-11 | Screening completed | 🔒 05-Apr-2018 | 🔒 05-Apr-2018 | 🔒 |
| 37 TEST-0001-12 | Screening completed | 🔒 05-Apr-2018 | 🔒 | 🔒 |

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.

FUNCTIONS AND PROPERTIES OF THE SYSTEM

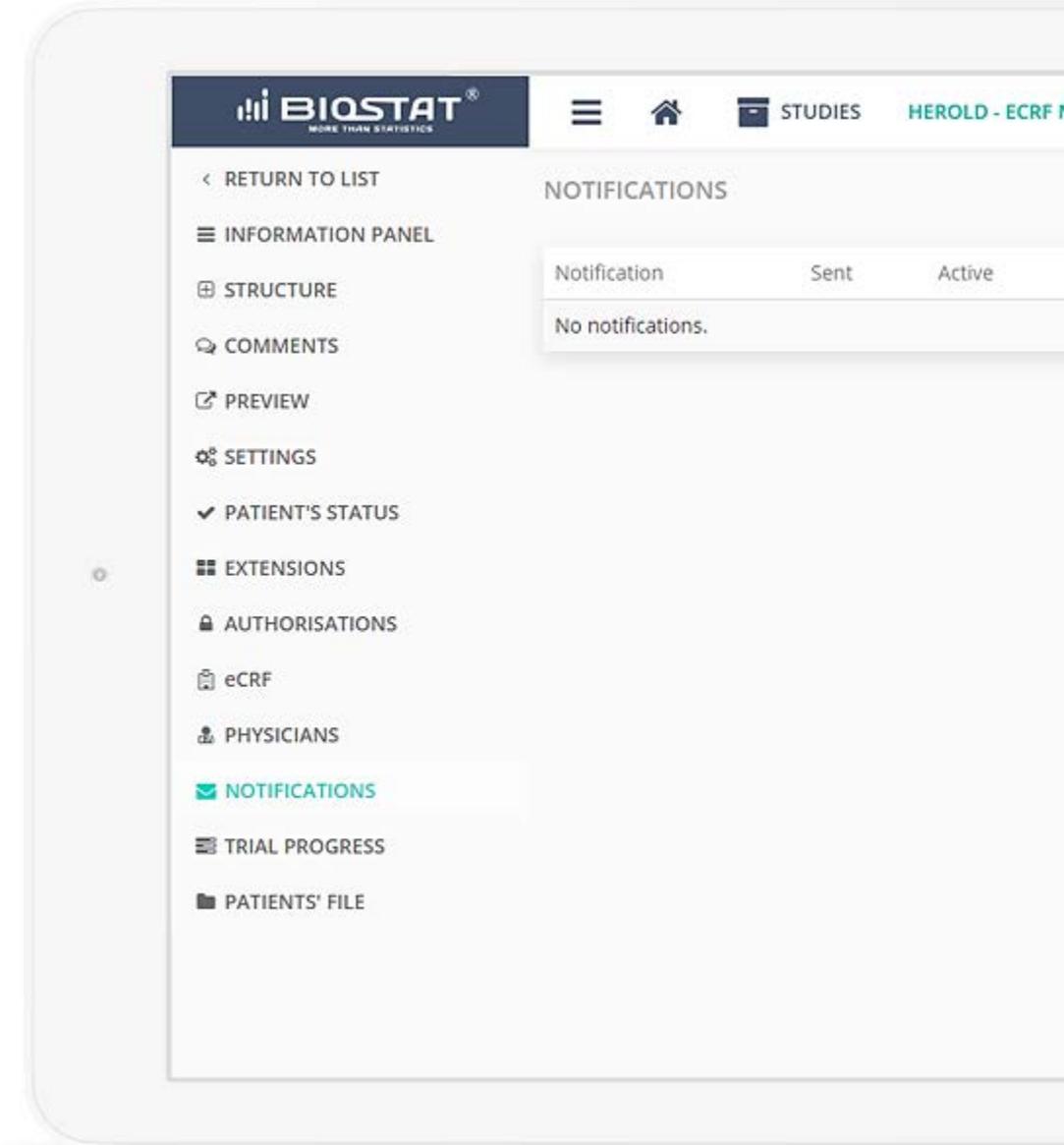
Notifications

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:

- 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



| ID | A | C | Status | Department | Expiration date | Visit | Date | Delete |
|----|---|------|----------|---------------------------------|-----------------|-------|---------------------|--------|
| 01 | A | 0 ml | Received | NHL-POL01 NHLPOL Katowice | | No | 2016-03-13 20:34 | Delete |
| 02 | A | 0 ml | Received | NHL-POL01 NHLPOL Katowice | | No | 2016-03-13 20:34 | Delete |
| 03 | A | 0 ml | Received | NHL-POL01 NHLPOL Katowice | | No | 2016-03-13 20:34 | Delete |
| 04 | A | 0 ml | Lost | NHL-POL01 NHLPOL Katowice | | No | 2016-03-13 20:34 | Delete |
| 05 | A | 0 ml | Received | NHL-POL02 NHLPOL Warszawa | | No | 2016-03-13 20:34 | Delete |

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.

FUNCTIONS AND PROPERTIES OF THE SYSTEM

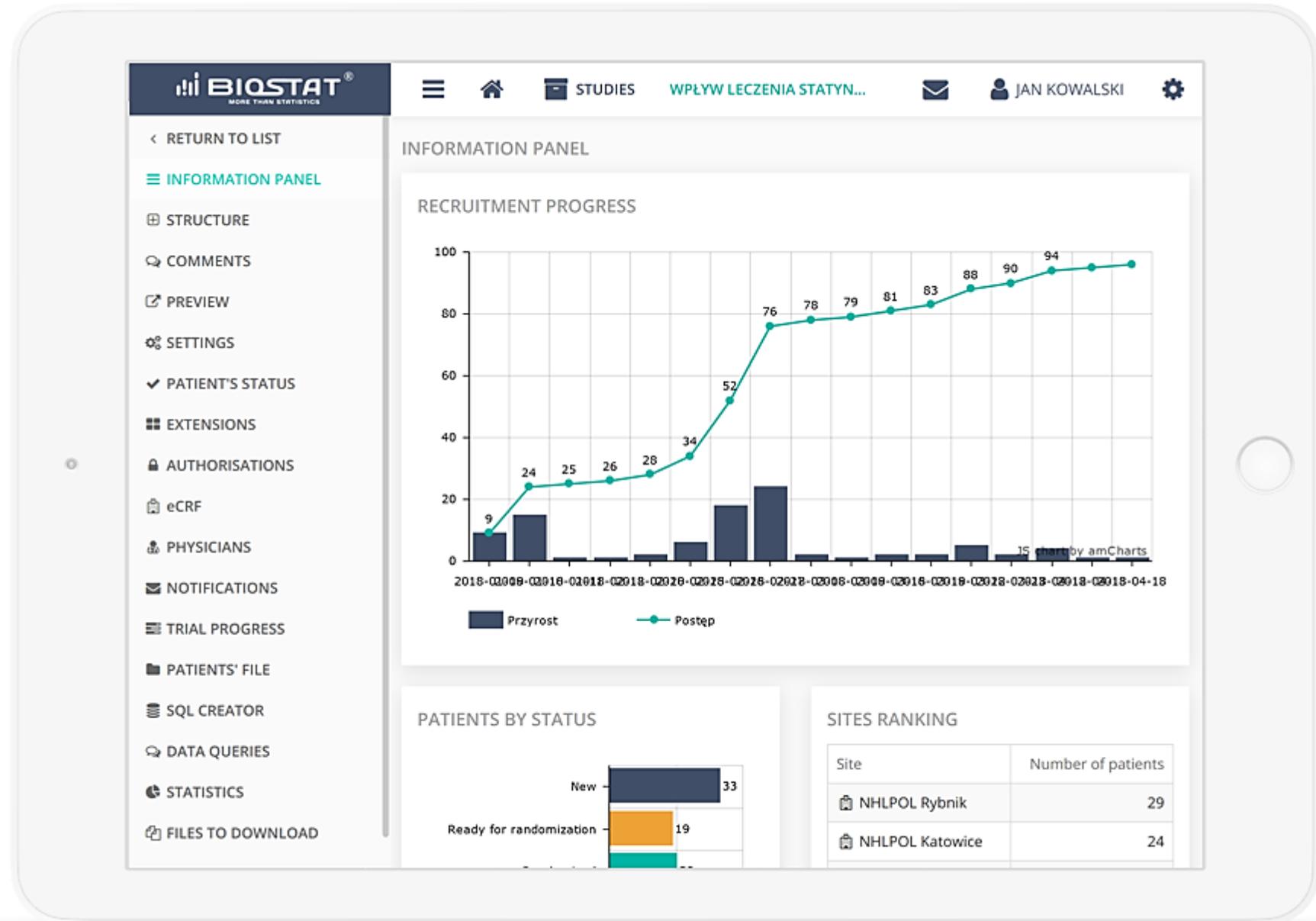
Reports

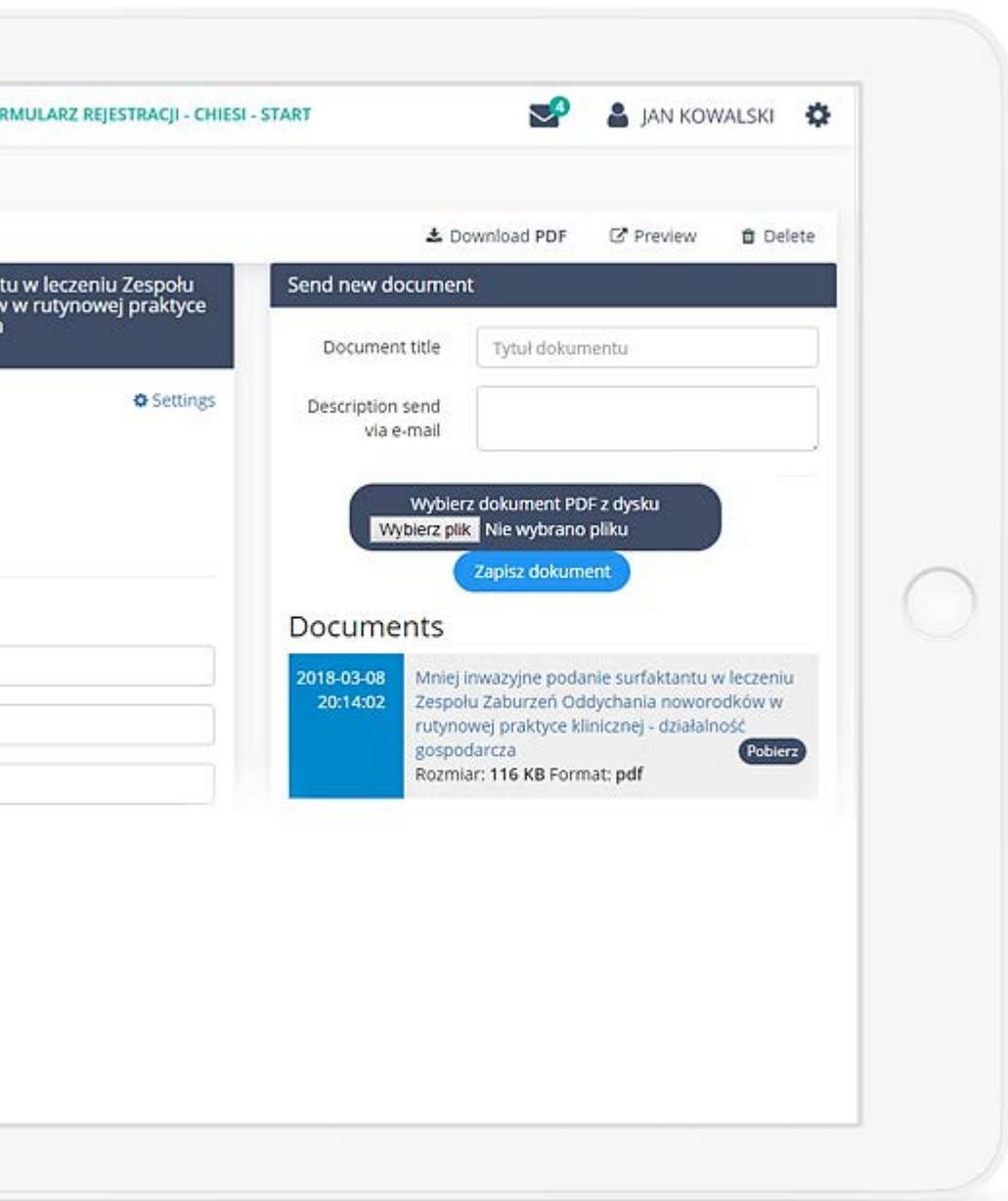
Reports on the basis of visits and selected questions (by using TWIG system for data generation).

Reports on the basis of SQL (administrator).

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

Reports on the basis of the sample analysis.





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 annexes – in case of research prolongation.

Positive opinion from DZP law agency.

Access code

Registration form

Receiving contracts on Emails

FUNCTIONS AND PROPERTIES OF THE SYSTEM

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



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



FUNCTIONS AND PROPERTIES OF THE SYSTEM

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



FUNCTIONS AND PROPERTIES OF THE SYSTEM



Remote access

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

FUNCTIONS AND PROPERTIES OF THE SYSTEM

Data backup

Data backup is processed in real-time.

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



Start

your work from
now on

with a powerful system for
gathering clinical data, and
join our satisfied group of
Clients.

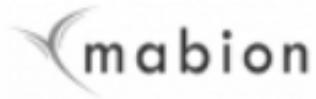


Our Clients

eCRF.biz™

"The level of eCRF™ 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 eCRF™ 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



Our Clients



NUMEROUS RESEARCH – ONE SYSTEM

**gain the upper
hand**



eCRF.biz™
electronic Case Report Form

BioStat Sp. z o.o.

☎ 48 668 300 664

✉ biuro@biostat.com.pl