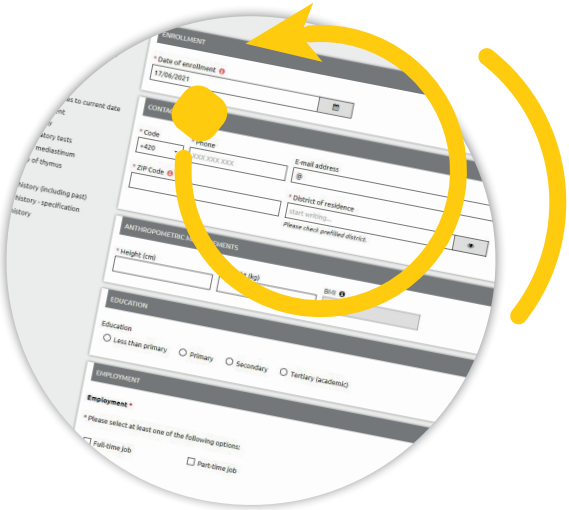
Institute of Biostatistics and Analyses

CHECKLIST FOR SELECTING AN ELECTRONIC DATA CAPTURE (EDC) SYSTEM AND CTMS THAT YOUR CRO WILL FIND EASY TO USE

And how a sound EDC system saves time, money and nerves

CHECKLIST



Must Haves:

1. Regulatory Compliance
2. Data Access Control
3. Robust yet easy-to-use eCRF designer
4. Multi-level data validation
5. Smart reporting

Nice-To-Haves:

1. SaaS deployment, maintenance & support
2. Wide-spectrum use
3. Configurable event triggers
4. Risk-based monitoring tools
5. Support of visual analytics
6. User-friendly experience
7. Interoperability & integration
8. CTMS features

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WAIT!

If you are looking for an EDC system that...

- is easy to use;
- has a user-friendly interface;
- gathers quality data;
- eliminates anomalous data;
- can store, handle and deliver data in a timely and feasible manner;
- has worldwide connectivity and real-time recruitment progress and status updates.

At the Institute of Biostatistics and Analyses, we have been looking for the same to fulfil our vision: HEALTHY DATA. If only there were a way to monitor, manage and process data, which CROs could use without slowing down.
Over the period of seven years, we have been working on this vision and finally brought it to reality. Tests after sprints, release after tests. Developing, deploying and maintaining until our dream of a smart data management platform became a reality. It is the EDC system that any researcher aspires to use and see results – containing such features as risk-based monitoring based on machine learning algorithms. Today, we are proud to present an EDC system that not only meets but exceeds the requirements and fulfils even the most complex data input: the CLADE-IS. Your EDC system on Steroids!

CLADE- IS developers: Institute of Biostatistics and Analyses (IBA)

The IBA team manages analyses and organises data in clinical research projects. IBA is a spin-off from Masaryk University. Starting in academia, IBA transformed theory with results from R&D to real-world application in society. And now, based on our experience, we have put together a list of features we need in our projects every day. Let's start with the must-haves.

THE ABSOLUTE BASICS for every EDC system

Issac, the top researcher at ClinicalRO (LLC), sat down again at his desk to drink his coffee. The last refreshing moment before his day of chaos began. Before turning on his PC, he took another breath to face the tangled mess of data facing him. He knew he would have to wade through data quality, validation and corrections. The EDC system he worked with had the minimum requirements:

1. Basic Regulatory Compliance
2. Security meeting the standards
3. An eCRF designer with multiple settings
4. Simple front-end error checks
5. On-demand reporting

But, this only provides the absolute basics. It is just the bare minimum – a little more than a glorified spreadsheet. It was like fighting a disease spreading before a vaccine could be made. And it infected every part of Isaac's work. Even if he were a team of robots, it would be too much. It was at that moment when Issac realised what he wanted. An EDC system that used AI. One that followed laws – just like the laws of robotics. Clean. Simple. Effective.

Robots

- **First Law**
  A robot must not injure a human or, through its inaction, allow a human to come to harm.
- **Second Law**
  A robot must obey the commands given to it by a human, except when those commands conflict with the First Law.
- **Third Law**
  A robot must protect its existence unless such protection conflicts with the First or Second Law.

EDC systems

- **First Law (Security)**
  The EDC system must not compromise data integrity or allow the user to cause a data security breach.
- **Second Law (Features)**
  The EDC system must accept a wide range of eCRF designs and provide data managers with a wide range of features for their creation.
- **Third Law (Quality)**
  The EDC system must strive for the highest possible data quality, even at the cost of using its artificial intelligence to detect data anomalies and other quality issues.

And just like Asimov's robots, he could interact with them getting clean and clear data = healthy data. It is not science fiction anymore. It is today's reality. That is why all EDC systems should not miss the following:

1. **Regulatory Compliance:** Meets EC – Directive 2003/94/EC Annex 11, USA – 21 CFR part 11. Contains audit trail – documentary evidence of all eCRF data transactions.
2. **Pre-secured Data Access Control:** User roles & permissions must be configurable and forms distinguished by statuses. All this needs to be highly secured, along with negative penetration tests and positive approvals from ethical hackers. The system must have regular releases covered with automated acceptance tests.
3. **Robust yet easy-to-use eCRF designer:** Hierarchical data entities, a wide range of question types, easy coding of skip logic & calculations, medical coding using multiple vocabularies, randomisation and multilingualism – all must be present.
4. **Multi-level data validation:** Simple front-end edit checks, complex back-end procedures, everything that needs to be done to make the data as healthy as possible.
5. **Smart reporting:** Fast and configurable data export, versatile data import.

Who works with EDC systems today?

EDC systems are not for everyone, not even everyone in healthcare. First, it is necessary to know if you need an EDC system and if the one you are using is appropriate for you in your clinical research practice (CLADE-IS may be just what you are looking for.) Here are groups that use IBA's EDC today.

- **Medical professional associations**
- Pharmaceutical companies
- **Biotechnological companies**
- CROs (contract research organisations)
- **Data managers and biostatisticians**
- Senior clinicians
- **Researchers**
- Medical experts

Do you belong in one of these professions or work with people who do? Then you will agree that settling for the basics will do no good. You want your project to run smoothly. And to do that, you will need some additional EDC features.

What advanced features do professionals look for in an EDC system?

Information overload scares many people – no matter who you are. In medicine, it is more prevalent than ever before. If you follow any news, you get the same message – mountains of opinions and no idea what the truth is. Whether the most current disease, vaccination or health data is being discussed, it is always the same. Everyone has their vision, but only a few see the actual situation. CROs find out, test and analyse which medicine and therapies are effective and not. It provides CROs with an overwhelming amount of data.

- **Taking notes**
- **Research**
- **Trials**

Issac does his best in clinical research but uses outdated systems all the while. It is a way to burnout and sick data. (We have had the same sickness – the same diagnosis during our clinical research.) Today, Issac faces the same problem as many other researchers: Clinical data management (CDM) is no longer just about EDC systems. That is why researchers are looking for an EDC system to take data and make it healthy.
By

- **Cutting through the irrelevant**
- **Presenting it by effective methods**
- **Having viability of use**

That way, people like Issac can work with data to benefit everyone in healthcare. (We at IBA had the same questions – the same problems. That is why we came up with CLADE-IS.)
When thinking about the EDC system, we found several essential features for it to be well-operable:

1. SaaS deployment, maintenance & support
2. Wide-spectrum use
3. Configurable event triggers
4. Risk-based monitoring tools
5. Support of visual analytics
6. User-friendly experience
7. Interoperability & integration
8. CTMS features

1 **SaaS deployment, maintenance & support:** The system must be cloud-based, with no need to buy servers or install the software. Beware: While your SaaS-based application will almost certainly be cloud-based as well, your cloud-based services may not always be SaaS-based – you should be able to consume regular releases with new features, initial training, plus continuous consultancy with senior clinical data managers.

2 **Wide-spectrum use:** Easily adjustable from real data projects to randomised clinical trials.

3 **Configurable event triggers:** Pharmacovigilance operations, patient invitations, general automated email reminders – all in the blink of an eye.

4 **Risk-based monitoring tools:** Artificial intelligence/machine learning algorithms for early detection of data anomalies. In the past, this meant that the time to detect anomalous data often took weeks or even months. Imagine reducing that time to minutes or seconds.

5 **Support of visual analytics:** Health professionals must be able to identify and analyse the data they receive at a glance. An EDC system that assaults with predefined reports made up of tables, numbers, and text is cumbersome and daunting. Therefore, the EDC system should be open to setting up interactive interfaces for analytical reasoning, and the tabular/graphical figures should have the ability to either be embedded or routed to an external web-based data browser.

6 **User-friendly experience:** Data input should be easy, with a logical layout of information. A responsive web interface accessible from anywhere (PCs, tablets, smartphones) and anytime (availability) is almost a must nowadays.

7 **Interoperability & integration:** The system must be open for seamless integration using the Rest API. For instance, integration to sophisticated external pharmacokinetic models, data exchange with cloud services providing information from wearable electronic and medical devices, etc. Additionally, up-to-date online documentation should be accessible for external developers to set up any such integration. CLADE-IS works seamlessly with all major manufacturers and any device on the market.

8 **CTMS features:** Dashboards, eTMF, management of site payments.

An EDC system worth using

Study design

Robust yet easy-to-use eCRF designer; Wide-spectrum use (Everything must be doable, FAST!)

Hypothesis

Regulatory Compliance; SaaS deployment, maintenance & support; CTMS features (The system must be regulatory-ready for your type of study. You should know that you can rely on it even before you start creating the study. Finding out that the system is not capable of organised documentation management can significantly slow down the course of your study.)

Data entry

Pre-secured Data Access Control; Configurable event triggers; Support of visual analytics; User-friendly experience (Doctors should not be limited by the system interface. Investigators should be able to see how data entry is proceeding.)

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Data validation

Multi-level data validation; Risk-based monitoring tools (All means to eliminate errors should be used.)

Data analysis

Smart reporting; Interoperability & integration (Automated data sharing for online analysis. Simple and readable export for easy processing.)

Clinical Data Warehousing Information System (CLADE-IS) – summary

We can't save the medical world from information overload.
However…
We save data management in clinical research and digital health with the CLADE-IS data management platform.

With CLADE-IS, data is faster to collect, of better quality and more manageable – this way, you can access it, process it with ease and be efficient in your profession. **It is a Clinical Trial Management System (CTMS) and an EDC System in one.**

The EDC system that...

- **Gathers Data**
- **Cleans**
- **Processes**
- **Accesses**
- **Identifies**
- **Analyses**

You want your data to be accessible, readable, and relevant to your work.
That is what CLADE-IS does for healthcare professionals, and it can do the same for you.
Now – take all your requirements and make them even more challenging.
Let us see if our CLADE-IS can handle them.

AI-powered, every day making life of researchers and CROs easier.

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References

“In the CLADE-IS system, we collect data in two monocentric clinical trials, FES2 and afECT. As we have thought about the design of these studies in our clinic for so long and thoroughly, we happily avoided collecting data on paper or in Excel – a variant that in the past led to many errors, data inconsistencies and disappointments. Now, we are enthusiastic about the possibilities of CLADE-IS.”

Prof. Tomáš Kašpárek, MD, PhD

- Vice-Dean for Science and Doctoral Studies, Faculty of Medicine – Masaryk University
- Head of the Department of Psychiatry
- Member of the committee of the Czech Neuropsychopharmacological Society

“I had an opportunity to test CLADE-IS on a project focused on data collection in pneumology and immunology. After testing several online eCRF systems, I can declare that CLADE-IS is a precisely designed system. The system has a well-developed user environment for both data managers and investigators. We will certainly use CLADE-IS in other studies that our company will cover.”

Katarína Breciková, PhD

- Project coordinator and associate researcher at CEEOR, spol. s .r.o.

Contact us

If CLADE-IS is what you are looking for, or if you have any further questions, you can book an appointment here:

For requesting our offer please visit us at **www.clade-is.com** in the section Request Offer.

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Daniel Schwarz
CIO
schwarz@biostatistika.cz

Institut biostatistiky a analýz, s.r.o. (IBA)
Poštovská 68/3, 602 00 Brno
Czech Republic
+420 515 915 100

biostatistika.cz
clade-is.com
info@biostatistika.cz

biostatistika.cz

info@biostatistika.cz

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