



How Your EDC Can Support Rapid FPI

A Guide
for Sponsors
& CROs

medrio



About the eBook

The first patient in (FPI) milestone marks a key moment in every clinical trial. It’s when months of planning, design, and coordination finally meet real trial participants. But reaching this point on time isn’t guaranteed—and when delays happen, they ripple across budgets, timelines, and confidence in the program.

Slow progress to FPI can stall momentum, inflate costs, and jeopardize funding. For smaller sponsors or CROs managing limited pipelines, those delays can threaten an entire study. Beyond the business impact, a delayed FPI also means patients wait longer for access to potential treatments and cures.

The pressure to meet FPI on time is huge. One of the main determinants of whether you’ll reach your targeted FPI is your EDC selection and configuration. This eBook shows you how to avoid technology roadblocks and use your EDC to accelerate the path to FPI.

In this ebook, you’ll learn:

- **Why FPI matters**
- **Various pathways to reaching FPI**
- **EDC best practices to reach FPI**
- **The role of your EDC partner in achieving FPI**

In this guide

- The Significance of FPI3**
- Various Paths to FPI.....4**
- EDC Best Practices to Accelerate FPI.....7**
- Preparing for Go-Live.....12**
- The Role of Vendor Partnerships in FPI.....15**





The Significance of FPI

Reaching FPI on time is more than a milestone—it's a signal that your study is ready to move forward. Rapid FPI builds confidence among sponsors and sites, and creates real advantages in cost, speed, and patient impact.

Proof of progress

FPI shows the world (and your investors) that your trial is truly underway.

FPI turns planning into progress. It marks the moment your study moves from preparation to purpose, proving your team's readiness and operational strength.

Patient access

Rapid FPI puts patients one step closer to new treatments.

Every day to FPI matters for patients waiting on new therapies. Fast activation means faster access to treatments or cures for those who need it most.

Fuel for growth

A fast start builds momentum—for your study, your sites, and your business.

Hitting FPI on schedule protects funding, strengthens site engagement, and keeps recruitment on track. It also gives you a competitive edge in a crowded market or cures for those who need it most.



Various Paths to FPI

Start on paper

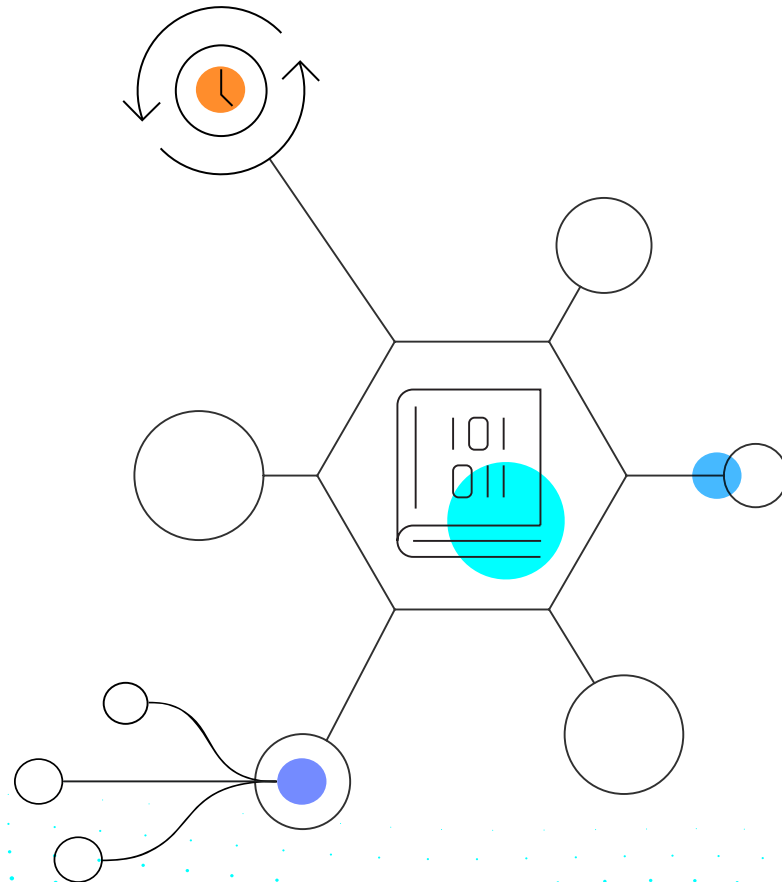
When the clock is ticking, it might seem tempting to default to paper. After all, it allows site activation while the EDC build is still underway. But this approach comes with significant cost later on.

Data must be re-entered or imported once the EDC is live—which means duplicate effort, extra validation, and possible transcription errors. Starting on paper also delays downstream visibility since your data isn't centralized until the EDC is up and running.



PRO TIP

Use this option only when startup deadlines leave absolutely no alternative, and plan the transition early. Also, adjust the budget to account for the rework costs.





Build a minimal EDC first

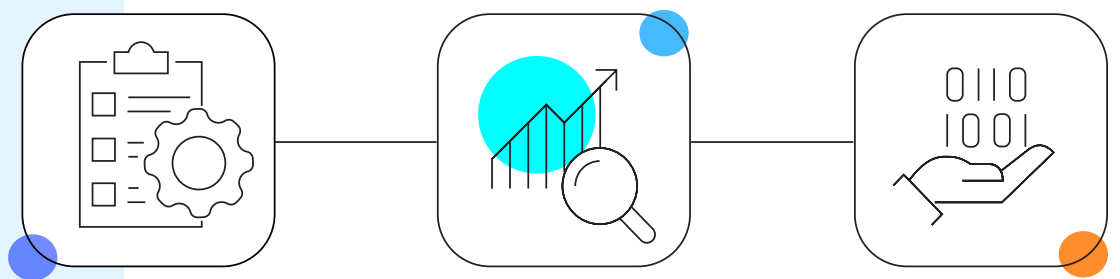
Teams focused on speed-to-launch may opt to build only critical forms. They may want to start collecting data quickly, and then layer on additional modules or edit checks later through mid-study updates.

While this approach might be faster than a full build, each update requires time for design, validation, and training. And every change carries a small delay risk—especially when multiple stakeholder reviews are required. Mid-study changes can also impact data that’s already been collected.



PRO TIP

This approach works best when timelines are aggressive but protocol changes are minor. Make sure your EDC has a validation environment that allows you to ensure changes won’t impact previously collected data.





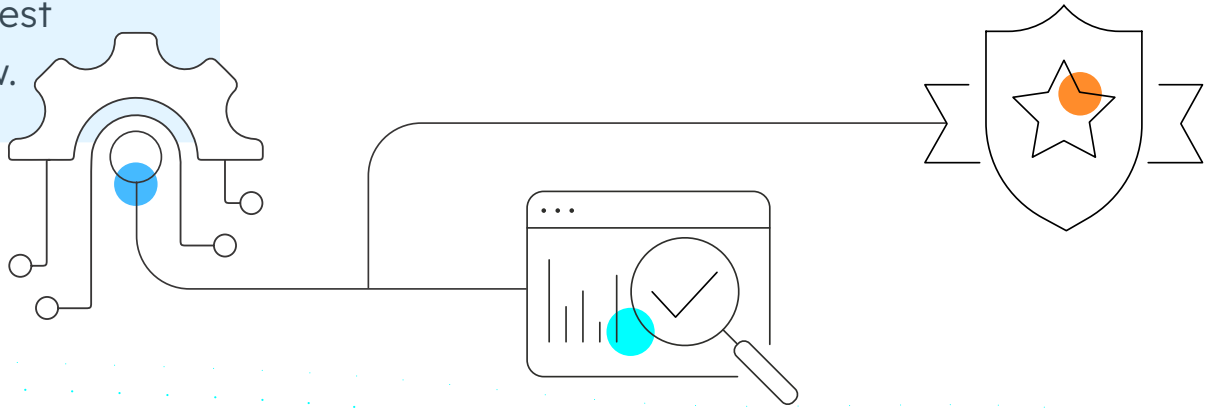
Build a complete EDC from the start

With a full EDC build completed, sites start with a system that is streamlined, tested, and ready for reliable data entry from the beginning. You also avoid the cost and disruption of repeated updates or validation cycles later. A complete build includes quality safeguards, such as edit checks and skip logic, which support faster downstream processes like cleaning, reviewing, and reporting.

To reach the full-build scenario, you need a stable protocol and early cross-functional alignment. Your data management and clinical operations teams must agree on how data will be collected, processed, analyzed, and stored. Meanwhile, your EDC vendor should deliver autonomous configuration, protocol-specific enablement, and responsive support.



PRO TIP
This approach is the **gold standard**. Choose a supportive EDC partner who can support your build and the FPI best practices explored below.





EDC Best Practices to Accelerate FPI

This section covers how to leverage built-in EDC features, anticipate integration challenges, and tap professional services—all strategies that help you go live faster and set your study up for FPI success.

Setting the foundation

A strong foundation is essential to reach FPI efficiently. Your protocol, data management plan, and early stakeholder alignment set the stage for a smooth, fast EDC build.

This section shows how to lock down core study elements, define mission-critical workflows, and coordinate teams upfront.

Bring stakeholders in early

Reaching FPI fast depends on early alignment. Every function—data management, clinical operations, biostats, and vendors—needs to agree on how a study will run. But when those conversations happen too late, it can mean that EDC builds stall, edits multiply, and timelines slip.

With everyone moving in sync, the EDC team can build faster, test smarter, and hand off a system that's ready for first-patient data—on schedule.



The best practice is to work from a finalized protocol that has been reviewed by the FDA, rather than a draft version. It is key to lock down the visit schedule and endpoints before beginning to build your EDC. Otherwise, the scope of the build can change and jeopardize the FPI timeline.

Bring stakeholders in early cont.

Bring key stakeholders together **before configuration begins**. Early decisions save time later by preventing rework and confusion.

Stakeholders need to agree early on about:

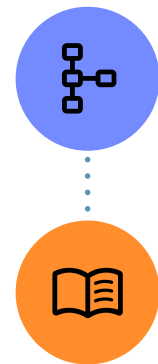
- ✓ **Key definitions** for endpoints, visit windows, and SAE rules
- ✓ **Data flow mapping** from the source to EDC and downstream systems like ePRO, RTSM, CTMS, safety database
- ✓ **Quality expectations**, including edit checks, query turnaround times, and missing data rules
- ✓ **Roles and ownership** for building, reviewing, and signing off

Stable protocol and data management plan

Your study protocol and data management plan (DMP) form the foundation of your study, and are tightly connected to reaching FPI.

- ✓ **The protocol is the blueprint.** It defines what data you need to collect, when, and from whom (visits, endpoints, safety measures, etc.).
- ✓ **The data management plan (DMP) is the execution manual.** It takes the protocol requirements and translates them into how the data will be captured, cleaned, validated, and reported in the EDC and other systems.

Therefore, **if the protocol changes late**, then the DMP has to be rewritten. If this happens, it usually forces changes to the EDC build, edit checks, integrations, and training. That creates rework and often delays FPI.





There can be a big cost and timeline risk to working with an “unstable” protocol. If your protocol finalization timeline changes, your FPI needs to adjust accordingly.



Identify mission-critical elements

When timelines are tight, every day matters. The best teams know how to focus on what truly drives FPI. That means identifying the core pieces of your EDC that are **mission-critical**—the forms, visits, and workflows needed to capture data from the first patient.

Nonessential forms or secondary modules can come later as mid-study updates. While flexible platforms can decrease risk and downtime associated with mid-study updates, study teams should still aim to build right the first time.



Identify what is essential to your build in order to capture data from your first patient.



Building a database with speed

Configuring your EDC quickly doesn't mean cutting corners. With the right approach, you can accelerate system setup while maintaining quality, accuracy, and control.



Leverage EDC features

Smart teams use every tool their EDC provides to move faster. Modern platforms make it possible to build, test, and deploy with minimal delay.

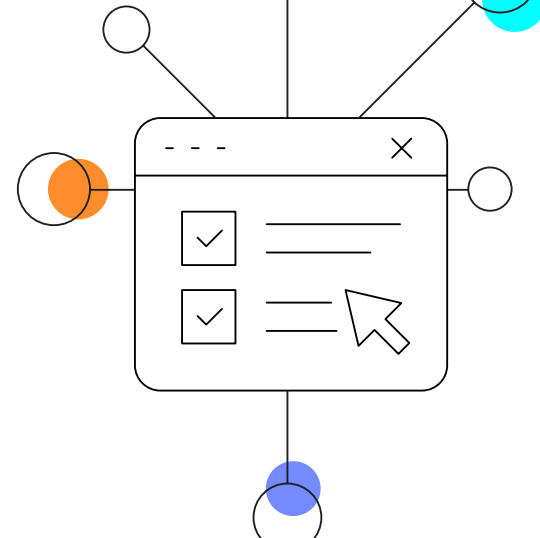
Consider these features to gain speed:

- ✓ **Bulk site addition** and **bulk user upload** can save hours of manual setup. These features let you onboard multiple sites and users in minutes instead of days.
- ✓ **Standardized templates and form libraries** cut build times and reduce errors.
- ✓ **Form previews** enable you to catch layout or logic issues early.
- ✓ **Role toggling while testing** verifies that permissions, workflows, and views work correctly for every user type.
- ✓ **Separate development, test, and validation environments** allow you to experiment safely without risking production data.
- ✓ **On-demand deployment allows** you to push your study live when you're ready—no waiting for vendor intervention.

Use every built-in EDC feature to your advantage. Automation, templates, and self-service tools can turn weeks of setup into days without sacrificing quality.



The right EDC features don't just speed up your study build. They'll also support quality data collection throughout your entire study.



The Importance of a Sandbox

Choosing an EDC with a free sandbox gives you hands-on experience before going live. You can explore features, test workflows, and identify potential issues without risking real data.

A sandbox lets your team build confidence, streamline setup, and ensure the system meets your study's needs before launch.

Anticipate integration challenges

Even the best EDC builds can hit roadblocks if integration isn't planned. Your EDC doesn't operate in isolation; it needs to work seamlessly with other eClinical systems, like eCOA, RTSM, and CTMS.

Anticipate interoperability issues early. Map out how data will flow between systems and identify potential points of friction. Common challenges include mismatched data formats, delayed updates, and workflow misalignment between platforms.

Address issues before they impact timelines. Build in validation checks, test data transfers in a separate environment, and confirm that all teams understand their roles. Proactively planning for integration keeps your study moving smoothly and protects your FPI target.

Plan EDC integrations early and test thoroughly. Anticipating interoperability issues prevents delays and keeps your study on track.



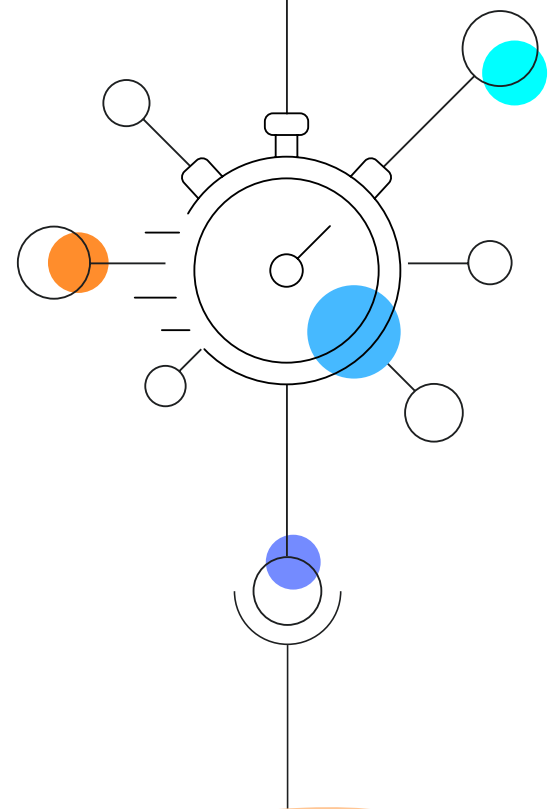
Benefit from professional services

Some EDC vendors offer professional services, sharing guidance on best practices and helping to optimize EDC features. Experienced services teams help new customers navigate the platform, shorten learning curves, and avoid common mistakes. Recruiting their help can make all the difference in achieving a fast, scalable build.



Using the same vendor throughout all study phases adds consistency and efficiency. Your professional services team knows your setup, workflows, and preferences, which speeds configuration, testing, and troubleshooting. It also makes scaling the study—adding sites, forms, or modules—faster and more reliable.

Engaging professional services early keeps your study on track, helps achieve FPI faster, and reduces risk across the trial lifecycle. Learn more about Medrio's Clinical **Trial Data Services** and **Clinical Trial Project Management**.



Build an EDC

that speeds,
not slows,

your path to FPI.





Preparing for Go-Live

Going live is a critical moment in any study. Proper preparation ensures your system is ready, users are confident, and workflows run smoothly from the first day.

This section covers how to plan and execute UAT, set up user management, and train all users—key steps that keep your FPI target on track and prevent avoidable delays.



Prepare for user acceptance testing (UAT)

UAT is your first real chance to see the system in action. It's where stakeholders get hands-on and verify that the EDC works as intended. Don't rush this process—skipping steps can lead to delays and more work later.

Include all stakeholders from the beginning. If someone joins mid-UAT, they miss the early context and may raise unnecessary issues. Regular check-ins keep everyone aligned and reduce surprises.

Start with a clear plan. Assign testing roles in advance so everyone knows what to review. Determine who will test which forms, visits, and workflows before Day 1 of UAT. Avoid figuring this out during testing—it only causes confusion.

Structure testing to be thorough and efficient. Document every finding, track issues, and confirm fixes. A well-planned UAT ensures the system is ready, builds confidence, and keeps your FPI target on track.

Thorough testing upfront keeps your FPI on track. Plan UAT carefully, include all stakeholders from the start, and assign clear roles.



Want to know more about UAT milestones?

→ [Check out our UAT in Clinical Trials Guide.](#)



Set up user management

User management needs to be done before sites go live. Proper setup keeps your study running smoothly from day one.

Assign the correct roles and permissions. Make sure site staff, monitors, and data managers can only access what they need. Verify accounts, roles, and permissions. Confirm that everyone can log in, enter data, and complete workflows without delays.

Plan and complete user setup early. Don't wait until the first patient arrives. Trying to add and configure user settings the same day a patient shows up creates chaos and risks data quality.

Set up user accounts, roles, and permissions early. Good user management ensures smooth study operations from the first day.



Train all users

Proper training prevents delays and errors. Site staff need to understand each casebook flow, because every protocol—and therefore every build—is unique.

Introduce training early. It's common to focus on the database build and go-live deadlines while overlooking user training. If coordinators don't know how to use the system, FPI targets can slip, even when go-live milestones are achieved.

“

Medrio's platform has shortened our development and validation timelines, giving us a strategic advantage in getting our medical device studies to market faster.”

- **Jared O'Donnell**, Data Manager at \$50M+ Medical Device company

Work with a vendor who offers customized training. Your team needs training tailored to your specific study and protocol. Feel comfortable building forms, but need help with reports? Partner with a vendor who can adapt your enablement sessions to spend more time on reporting and less time on configuration.

Leverage Medrio's training tools. Medrio eLearning gives users access to courses covering configuration, workflows, and data entry. Certificates of completion are returned to Medrio to confirm readiness.

Effective training ensures users are confident, workflows run smoothly, and the system delivers immediate value. Work with a vendor that can provide tailored, protocol-specific training to achieve the maximum benefit.





Our relationship with Medrio helps us decrease timelines, especially with regard to study builds.

Instead of taking 16 weeks, we've built studies in 10 to 12 weeks.

Plus, real-time data management keeps our data clean and decreases database lock time. It's a huge success!

- Frances Rubenstein, PhD.,
Director of Clinical Operations at \$1-5M CRO

The Role of Vendor Partnerships in FPI

Achieving FPI isn't a solo effort. It requires collaboration between sponsors, CROs, sites, and technology vendors. A strong, collaborative relationship with your EDC provider can accelerate timelines, reduce errors, and help your team stay focused on what truly drives first-patient enrollment.

Medrio takes this partnership approach to the next level. From pre-sales through study execution, we provide upfront support to get teams started quickly. Our guided sandbox experience allows new users to explore the platform, test workflows, and even begin building before signing a contract. This early engagement shortens the learning curve and sets the stage for a fast, confident start.

Reach out to Medrio's experienced team to get to FPI faster.
[Schedule a demo with us.](https://medrio.com/request-demo/)
<https://medrio.com/request-demo/>

