Five Quick Tips to Accelerate Your Study Build

Accelerating study build times became an imperative during COVID-19. Delivering faster study builds has since propelled the adoption of new technology, processes, and resources.

Study build teams are required to simplify and future proof design to save downstream time and costs. They also have an opportunity to gain greater control of study data and execution, optimize the entire trial lifecycle, and accelerate time-to-market.

While speed prevails, study build teams need to ensure study integrity, patient safety, and regulatory requirements. The technology strategy they choose, the approach they take, and the specialists they partner with drive the pace, data integrity, and successful outcomes of their trials.

This eBook outlines five specific tips you can apply to accelerate and optimize your study builds today, and into the future.

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UNDERSTAND NEW STUDY BUILD CHALLENGES

Study builds are core to ensuring the integrity and accelerating the pace of clinical trials.

Yet, new challenges can affect the quality of a build and impact the outcome of a trial.

Always faster

The first challenge is continuously shrinking timelines. Everyone wants faster builds. Increasingly complex builds are expected to be completed in less time and with fewer resources.

More integration requirements

As a result of the COVID-19 pandemic, study build teams are being asked to respond to quickly increasing decentralized clinical trial (DCT) requirements. Those lead to complex integrations across an ever growing number of systems trying to communicate with each other. To ensure data integrity, more vendors require alignment, defined roles and responsibilities, additional documentation, and often challenging orchestration across time zones.

Adjusting to adaptive trials

Study build teams are also faced with adjusting to adaptive trials, which require changing a trial design based on the data being captured and analyzed, leading to changing protocols.

As a key part of design requirements for databases, protocols need to be built so they can evolve in a flexible manner while ensuring electronic Case Report Forms (eCRFs) can be captured accurately and efficiently.

TIP ONE

REQUIREMENTS GATHERING AND KICKOFF

PLAN

- Meet to initiate project
- Gather requirements
- Define critical success factors
- Establish sponsor project team, responsibilities, and working relationships
- Develop program, schedule, and communication plan

Measure twice. Cut once.

While timelines are becoming tighter than ever, get your study build off to a strong start by investing enough time in the requirements gathering kickoff.

Spending the right amount of time upfront will ensure avoiding errors and delays in downstream configuration. While the main focus tends to be on the 'first patient in' goal, requirement gathering and kickoff planning can not be rushed.

Achieving a higher degree of timeline success requires you to:

Ensure all stakeholders participate

All parties must be included in kickoff meetings. Avoid proceeding without your key partners or vendors responsible for different areas of integration/delivery. When everyone is at the table from the start, key decisions do not need to be revisited.

Set detailed expectations

Define clear roles and responsibilities. Who will play what role throughout the entire lifecycle of the project? Who will be responsible for testing? How will dependencies work and evolve?

Create realistic timelines

You can create any timeline at the beginning of a project, but as the trial evolves, an activity can get delayed or a vendor may miss deadlines, cascading into downstream effects. Plan for success from the start.

Clarify requirements

An internal review of requirements before configuration takes place must be vetted upfront by key people before they're turned into solutions and study build.

To avoid rebuilds and save time, ensure clear requirements around both upstream and downstream integrations.

TIP TWO

STANDARDIZE STUDY BUILDS

BUILD

- Study design specification
- eCRF and single fields edit checks
- Dynamic edit checks and visit schedule
- Data validation specification
- Configured edit checks and custom functions
- Clinical views
- Global reports

Avoid reinventing the wheel. Standardize utilizing company standards, client standards, or industry standards, such as CDASH, to help align all stakeholders around a consistent way to collect data.

Formats and structures are set to provide clear traceability of submission data into the Study Data Tabulation Model (SDTM). Using CDASH delivers more transparency to regulators and others who conduct data review.

Gain clarity in each step

Once you select and apply a specific standard for the course of your clinical trial, have clarity in each step. It will enable you to use pre-built edit checks, load directly, and pre-test to reduce times in building and testing.

Streamline and automate

Using features within a platform enables you to streamline the build, set variables, and run checks at different variable levels. Use dynamic features to reduce the number of unique forms.

Leverage global libraries

Using global libraries simplifies study builds and ensures that studies utilize standard forms and processes. This results in less redundancy, greater standardization, and faster startups to deliver timely releases.

Maximize reuse

Maximize reuse to minimize effort and testing. It will enable you to carve out time to develop more complex, customized pieces of work.

TIP THREE

WORKABLE STUDY DESIGN COLLABORATION

USER ACCEPTANCE TESTING / DEPLOY

- UAT checklist provided
- Study build testing
- Data upload testing
- Site communication and training
- Freeze legacy data entry
- Cutover strategy
- Post data upload cleaning strategy
- Minimize site downtime

Collaboration is the number one driver for a successful build.

The mindset of “One Team with One Deliverable” across multiple groups and organizations will ensure transparency, accountability, and agility during study build and throughout the trial journey. Collaboration is facilitated through specific approaches.

Systematize interactive reviews

Keep ongoing interactive reviews of builds, especially with key decision makers, to share, review, and approve each decision and step preceding the study build.

Ongoing reviews will also accelerate formal testing and approvals, and help move through timelines at a faster pace.

Reconcile differences

Consolidate findings to reconcile differences. Many stakeholders will do testing and come up with different results.

Using tools such as Rapid Study Builder will consolidate findings, enable reporting, track changes, avoid duplicate iterative recycles, and document full audit trails in real time.

Test end-to-end

As you prepare for User Acceptance Testing (UAT), execute an end-to-end testing of one patient all the way through the lifecycle of their time on the study.

Create a patient in the system all the way through the lock and pull out reports to mimic production, so that when you do go live, there are no last minute surprises.

TIP FOUR

LEVERAGE TECHNOLOGY BEST PRACTICES

DATA CONTROL — EXTRACT, TRANSFORM, AND LOAD

- Extract data from source system
- Author data transformation scripts, as needed
- Transform data into target formats
- Map data using Batch Upload Tool
- Determine sequence of data load
- Perform dry run of data load

When your technology is able to extract what is needed from its source system, information is easier to access and data transformation scripts become more efficient.

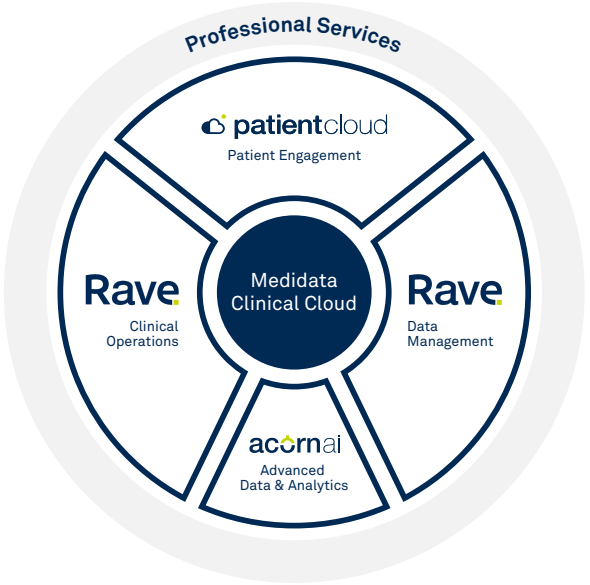
The right technology can also transform that data into target formats, and map it together using a batch upload tool.

Control your data

Getting the most out of your build's workflow means applying a basic formula for extracting, transforming, and loading your data.

Simplify integrations

A single, integrated platform eliminates multiple steps throughout the lifecycle of your study build and results in reduced build times, trial length, effort, errors, and costs.



Connect everything

When your clinical systems (EDC, RTSM, eCOA, etc..) are all connected in a unified platform approach, all process data—from patient consent to supplier management—flows across the systems.

Remove additional integrations from your build's equation and minimize disruption.

TIP FIVE

CHALLENGE THE STATUS QUO

FUTURE-PROOF BY SIMPLIFYING TECHNOLOGY

- Design for end-to-end implementation
- Avoid unnecessary programming and risks
- Centralize and supervise data access
- Eliminate inefficiencies around technology integration
- Reduce reconciliation risks from non-standardized data

Timelines for clinical trials are not expanding. If anything, they are getting shorter. And, complexity is rising.

Rather than stopping at celebrating bare minimums of meeting timelines and budget goals, the question should always be: how can we do better?

Embrace new technology

Is there technology that we can leverage to be even faster and more efficient?

Complacency when it comes to evaluating and rethinking the technology with which we've become accustomed is detrimental to 'doing better'.

Take an iterative approach: are we really looking to see what happened with that previous build and how can we be even more efficient going forward? Think: Global libraries. Connected workflows. Common system languages. Automated real-time visibility and decision-making.

Flexing to new processes

The way we've always done it isn't necessarily the way we should continue to build studies.

The speed of clinical trials and expectations of patients, sites, researchers, sponsors, and contract research organizations is rising exponentially.

Initiating processes that focus on what went wrong, in addition to what went well, will inform and help define new, more efficient approaches to study build and clinical trial execution.

Look back to move forward

Take time to do an internal process audit at the end of a project.

Look back and see what happened to figure out how you can gain efficiencies moving forward.

BUILD TO ACCELERATE TIME-TO-MARKET

Speed will continue to prevail, as expectations to accelerate time-to-market are increasing.

Study build teams have options in technology, in processes, and in resources to ensure study integrity, patient safety, and regulatory requirements.

Apply all tips shared to improve your study builds: increasing your Library, working on a platform approach, planning better upfront. Those areas on which you can reflect to create new efficiencies for even quicker builds will determine the success of your clinical trials moving forward.

While top-notch technology may require a higher outlay upfront, it will help you avoid troubleshooting down the line, hours of effort to work within disparate systems, and platforms that don't communicate.

The Study Build approach and technology strategy you choose, the approach you take, and the specialists you partner with will drive the pace, data integrity, and successful outcomes of your trials.

FIVE QUICK TIPS TO ACCELERATE YOUR STUDY BUILD

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