# HSA-NHG-CRCS Forum

***Ensuring Data Governance When Using REDCap for Investigator-Initiated Trials***

**30 September 2026**

# How to Build a GCP-Compliant REDCap Project

*Doing it right. From the very first click.*

**Presentation Slides + Notes Handout**

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## Introduction

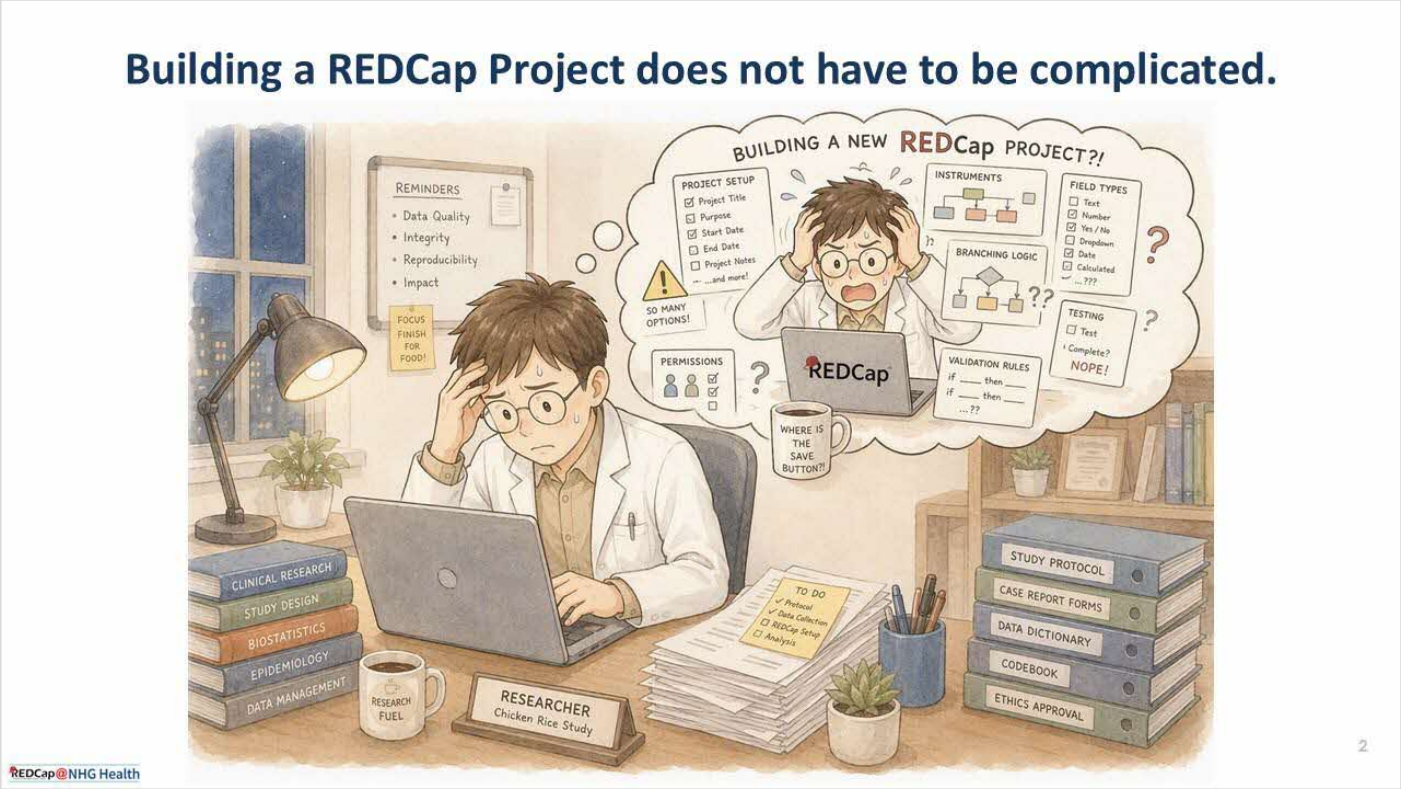
- This presentation introduces a practical approach to designing and managing REDCap projects in a way that supports a study's data collection requirements and meets Good Clinical Practice (GCP) principles.

- Although REDCap is widely used as a data capture platform, a successful REDCap project requires more than simply replicating hardcopy forms as electronic forms. Study teams must also consider data quality, user access, workflows, compliance requirements, testing, training, and ongoing maintenance.

- Rather than deep-diving into the technical 'how-tos' of a REDCap project build, this presentation walks through the thinking and key considerations behind a structured six-step process — one that can be applied to REDCap projects of any size and complexity.

- The overall objective is to show that building a GCP-compliant REDCap project does not need to be complicated, provided a logical and systematic process is followed.

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**Building a REDCap Project Does Not Have to Be Complicated**

- Many researchers approach REDCap project development with some degree of stress, particularly if they are unfamiliar with system design or database concepts and have only a basic knowledge of using the REDCap system.
- Questions often arise around what should be built, how forms should be structured, what data fields should be used, and what level of documentation is required.
- While gaps in REDCap technical knowledge can usually be addressed with support from your REDCap Administrator, this means little if the study team does not have a clear understanding of their own study protocol.
- Most REDCap projects can be developed successfully when the work is broken down into smaller, more manageable stages.
- Rather than attempting to solve every problem at once, study teams benefit from following a clear sequence of activities that guides the project from planning through to deployment.
- The key message here is that REDCap project development is more straightforward when approached systematically.
- Good project outcomes are usually the result of good planning, not technical complexity.

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**The Six-Step REDCap Build Process**

- The six-step process consisting of Analyse, Build, Test, Deploy, Review, and Amend. These six steps provide a simple structure that helps guide the lifecycle of a REDCap project.

- Each step builds upon the work completed in the previous step, creating a logical flow from project conception through ongoing maintenance.

- One of the strengths of this framework is that it emphasizes preparation before action. Activities such as understanding requirements and testing functionality occur before a project goes live, reducing the likelihood of costly corrections later.

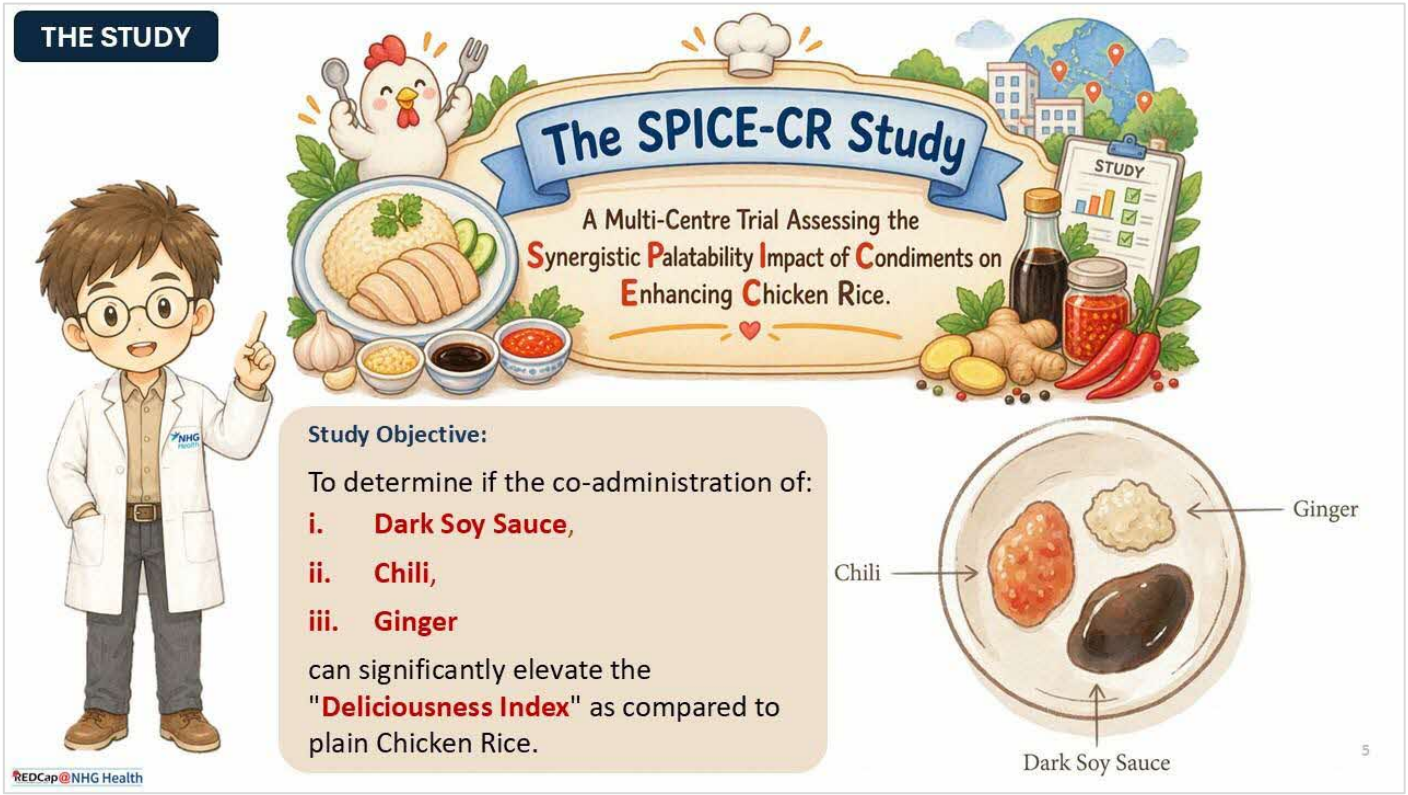
- Importantly, the framework should not be viewed as a one-time process. Most research projects evolve over time as study requirements change, operational challenges emerge, or improvements are identified. Continuous review and controlled amendment remain essential throughout the life of the study.

- By following a consistent framework, study teams can maintain control over project changes while supporting data quality and regulatory expectations. The framework also provides a useful common language when discussing project progress among researchers, coordinators, and administrators.

- When followed consistently, this process helps ensure that the data collected within the REDCap project is accurate, complete, and reliable — supporting the overall integrity and documentation of the study dataset.

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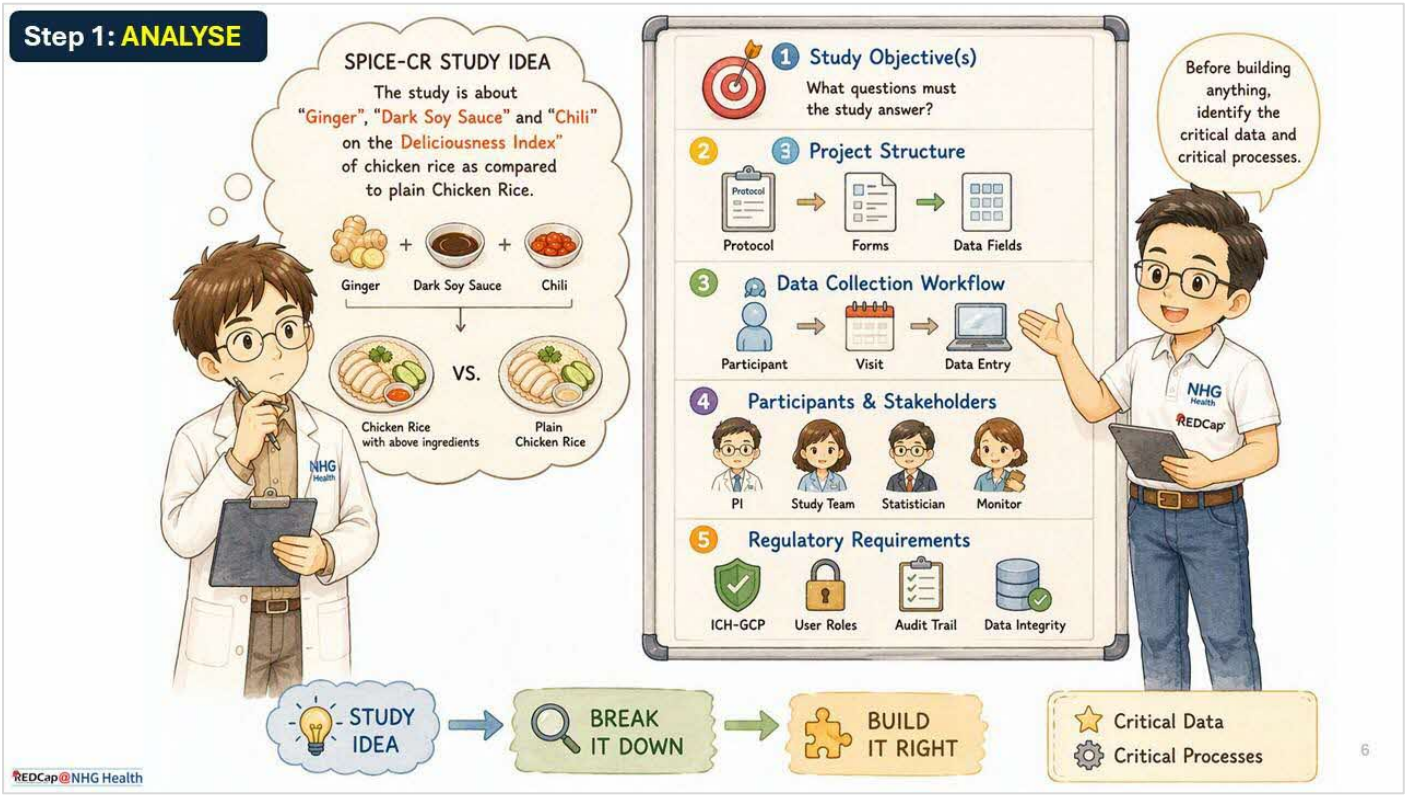




**Introducing the SPICE-CR Study**

- To make the concepts easier to follow, we will use a fictional study known as the SPICE-CR Study to illustrate how the six-step process is applied in practice. The SPICE-CR Study investigates whether adding certain condiments to chicken rice can influence its "Deliciousness Index."

- The study objective may appear straightforward. However, even simple studies require decisions regarding participant data, assessments, study variables, user workflows, and reporting requirements — and these decisions ultimately shape how the REDCap project should be designed.

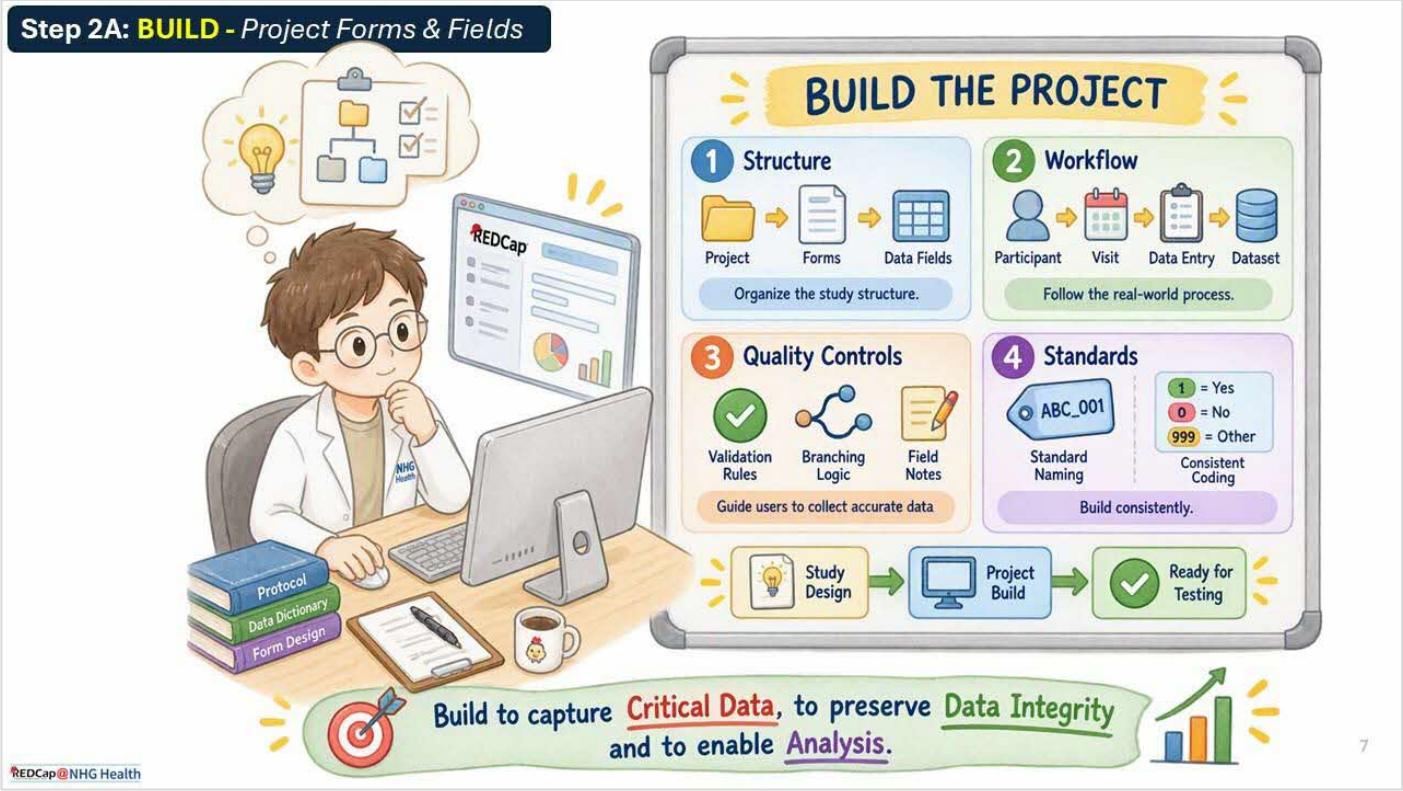
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**Step 1: Analyse – Understanding the Study Requirements**

- The Analyse step is often the most important step of the entire process.
- This is where study teams identify and document what information must be collected (Critical Data Points), who will use the system (Stakeholders), how data will flow through the study (Critical Processes), and what compliance requirements (IRB, HSA, etc.) need to be met. These findings should be captured in a study requirements document.
- A common mistake is starting the REDCap project build too early. Without clearly defined requirements, study teams will frequently find themselves making repeated changes later, increasing both workload and risk.
- Investing additional effort during the Analyse step to fully understand the study requirements and produce a detailed requirements document will often save considerable time and effort during project development, testing, and deployment.

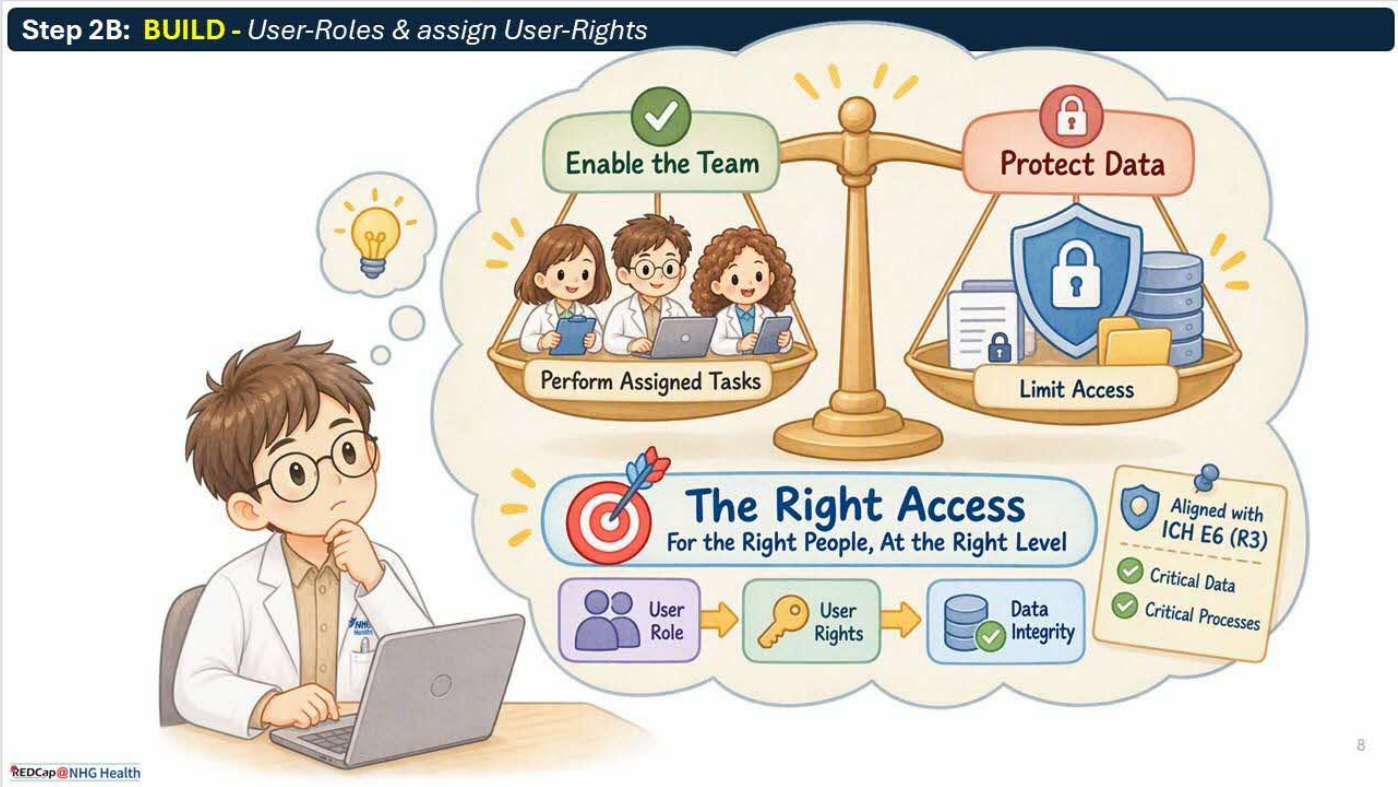
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**Step 2A: Build - Creating the REDCap Project**

- Once requirements have been defined and signed off, attention can shift to building the REDCap project itself.
- This stage includes creating data collection forms, defining field types, applying validation rules, configuring branching logic, and establishing the overall project structure.
- Each design decision should support accurate and consistent data collection, which will ultimately help answer the study question.
- At this step, the technical skills of the REDCap Project Builder become important. Project Builders should attend REDCap training where available. When in doubt, they can seek help from their REDCap System Administrator. The internet, and increasingly AI, is also a rich source of REDCap information and guidance.
- Good project design is not simply about entering information into REDCap. The goal is to make data entry intuitive for users while reducing opportunities for errors. Well-designed forms support both efficiency and data quality.
- Careful planning during the build phase contributes significantly to long-term project success.
- The goal is to create a system that captures high-quality data accurately, consistently, and efficiently.

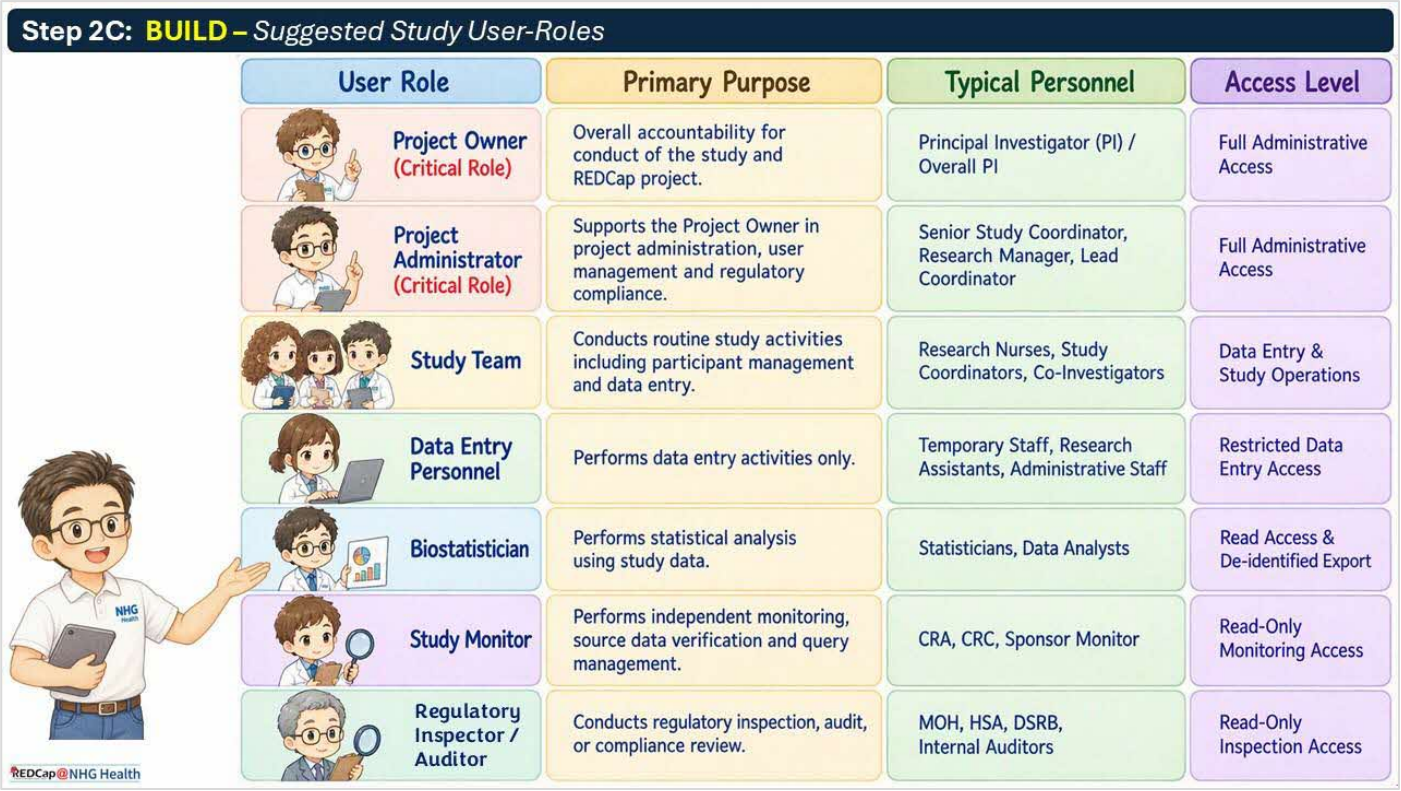
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**Step 2B: Build – Managing Users, User-Roles & User-Rights**

- User access is an important component of both security and regulatory compliance. Different members of the study team have different responsibilities and therefore require different levels of access within the project.
- The Principle of Least Privilege is particularly important here — *not everyone needs access to everything*.
- For example: *Should a temporary staff member employed for data entry be able to export data from the project?*
- Users should receive sufficient permissions to perform their duties, but no more than necessary. This helps reduce accidental changes, protects study data, and simplifies project governance.
- User access should also be promptly updated whenever there are changes to the study team or to their responsibilities within the study.
- Appropriate role-based access improves accountability and traceability by ensuring that activities within the system can be clearly attributed to specific users and their responsibilities.
- The objective is to provide the right access to the right people at the right level.

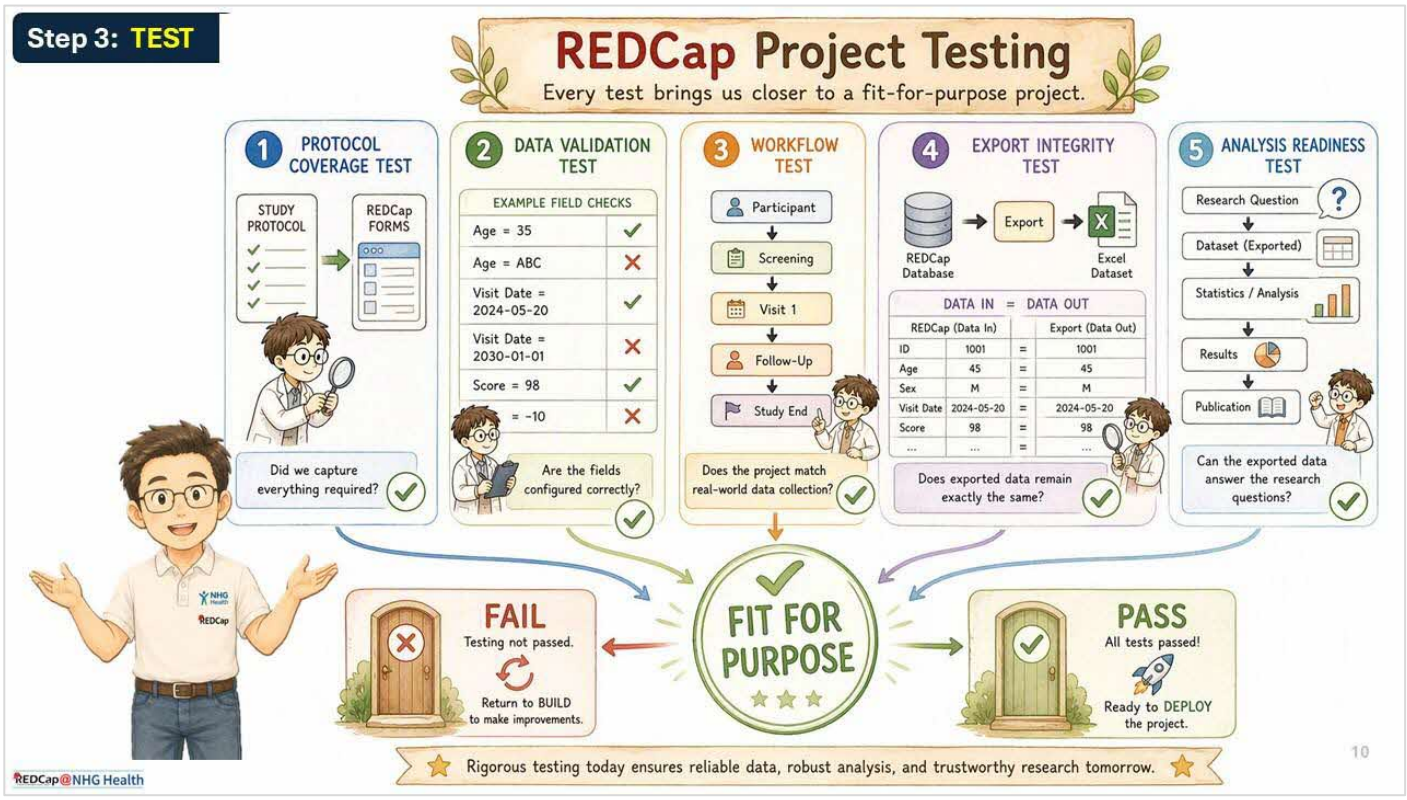
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**Step 2C: Build – Suggested User-Roles & their purpose**

- This slide presents an example of how common User-Roles can be mapped to REDCap project permissions and responsibilities.
- Rather than assigning User-Rights individually to each user, it is generally more efficient to create standardised User-Roles. These can then be reused consistently whenever new users require access.
- Builders should pay special attention to the following critical User-Rights in a REDCap project:
  - Project Design & Setup
  - Access to the Project's User-Rights module
  - Data Import / Export
- These critical User-Rights should not be granted broadly and should be restricted to the Project Owner and Project Administrator only.
- A role-based approach reduces administrative effort, minimises User-Rights assignment errors, and creates a more organised access management process. It also helps auditors and inspectors understand how permissions are controlled within the project.
- Project Owners should be prepared to justify to auditors and inspectors how User-Roles and User-Rights have been assigned across the study team.
- All study team members should have their assigned User-Roles, User-Rights, and responsibilities documented in the Study Delegation Log.

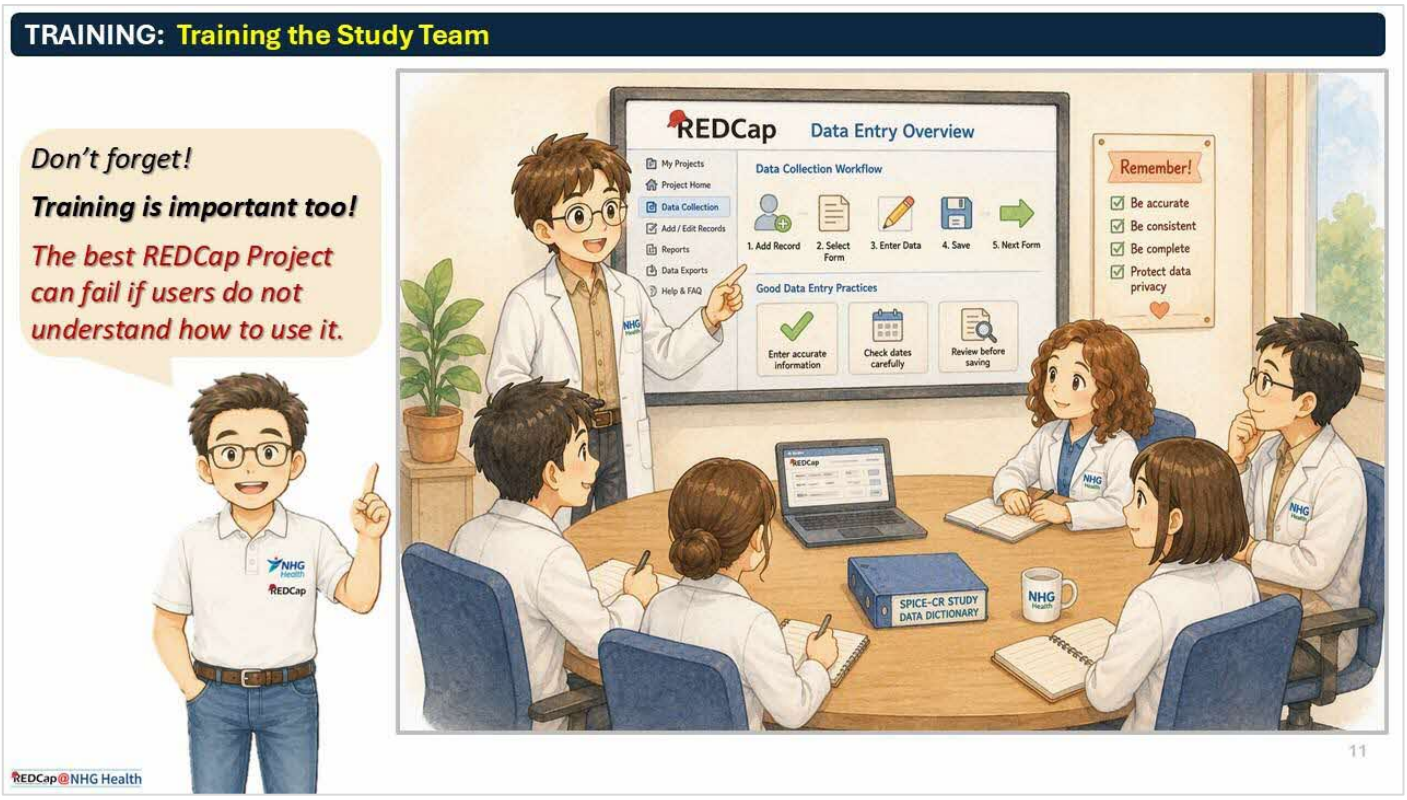
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**Step 3: Test – Is the project fit for purpose?**

- Testing, or User Acceptance Testing (UAT), is a critical step before a REDCap project is released for operational use and actual data entry.
- Testing cannot be conducted by the Builder alone. Ideally, it should involve the study team members who will actually be using the project.
- Testing allows study team members to verify that forms, calculations, validation rules, workflows, and permissions function as intended and are fit for purpose as required by the study protocol.
- Testing should cover both expected data and workflows, as well as unusual scenarios with unexpected or incorrect data and processes, which may reveal hidden issues.
- The objective is not merely to confirm that the project works — it is to identify weaknesses while changes can still be made safely and efficiently. Finding issues during testing is far preferable to discovering them after data collection has begun.
- The UAT document should be based on the study requirements identified in Step 1 – Analyse, and all test results should be documented.

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**Training the Study Team**

- Before the study team can test the project or begin data entry, the Builder must first train them on how to use the REDCap project.
- Training provides an opportunity to demonstrate workflows, explain project expectations, answer questions, and reinforce good data entry practices and workflows. It also helps identify misunderstandings before they lead to data quality issues.
- For complex projects, it is worth developing a training programme or user guides that can also serve as a reference and onboarding material for new team members.
- Training should also take place when significant changes have been made to the project.
- A well-trained study team is typically more confident and more efficient when using the system, resulting in fewer user-related errors and less corrective effort during the study.
- Training should therefore be viewed as an essential and ongoing project activity, not an optional extra.
- A well-built project with an untrained team will still produce poor quality data.

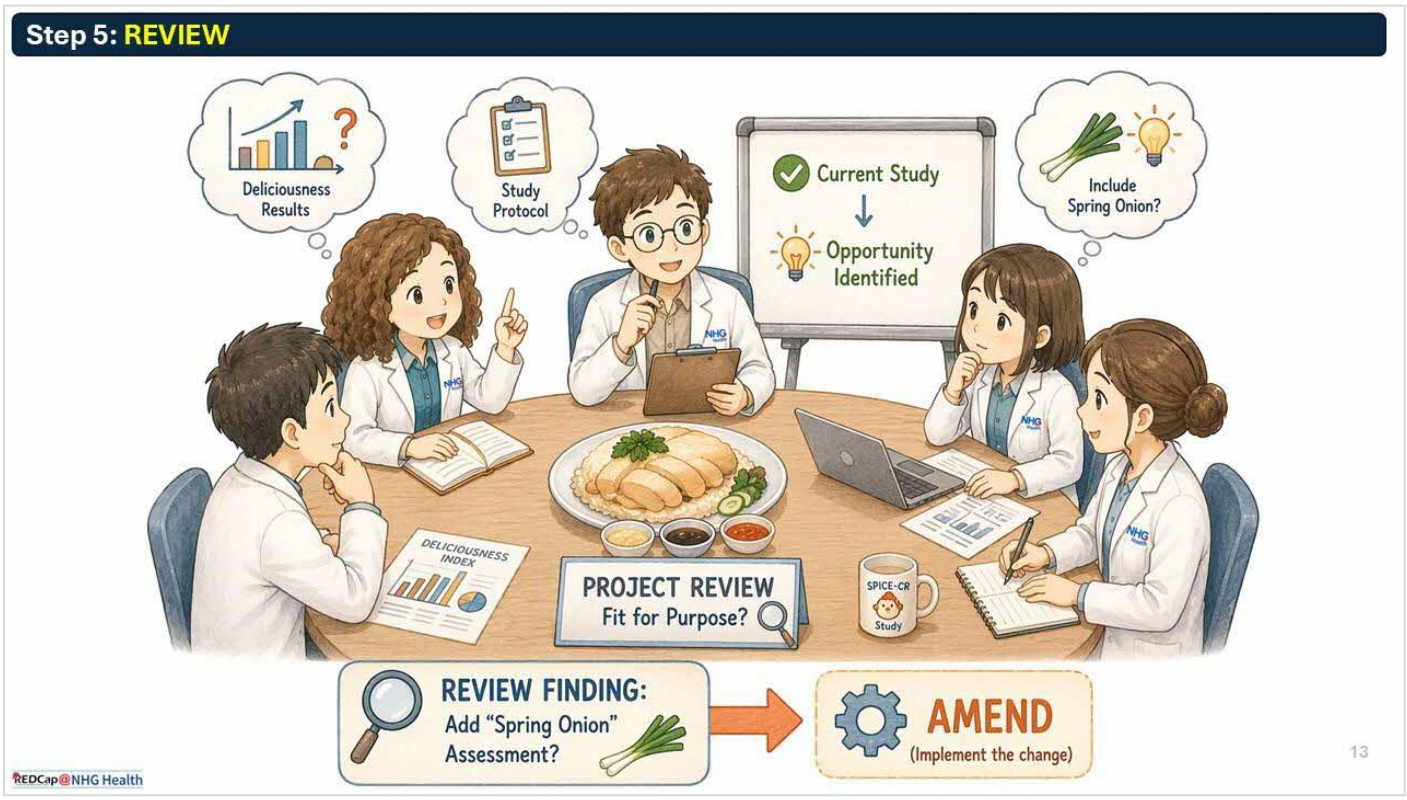
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**Step 4: Deploy – Getting ready to start data entry**

- Deployment marks the transition from project preparation to active operational use.
- Before deployment, study teams should ensure that testing has been completed, regulatory approvals are in place, user access has been verified, and relevant documentation is available. These activities help support a controlled and well-managed go-live process.
- For REDCap projects, the final practical step is to switch the project status from Development-mode to Production-mode.
- Production-mode activates safeguards that prevent accidental changes to the project. If the project remains in Development-mode, such changes could result in data corruption or loss.
- Switching the REDCap project to Production-mode also provides the opportunity to reset the project's record numbering sequence and to delete all test data, giving a clean slate for actual data collection.
- Although deployment is often viewed as a major milestone, it should not be seen as the conclusion of project development.
- Once data entry begins, additional observations and improvement opportunities will often emerge — at which point the project moves into the next step: Review.

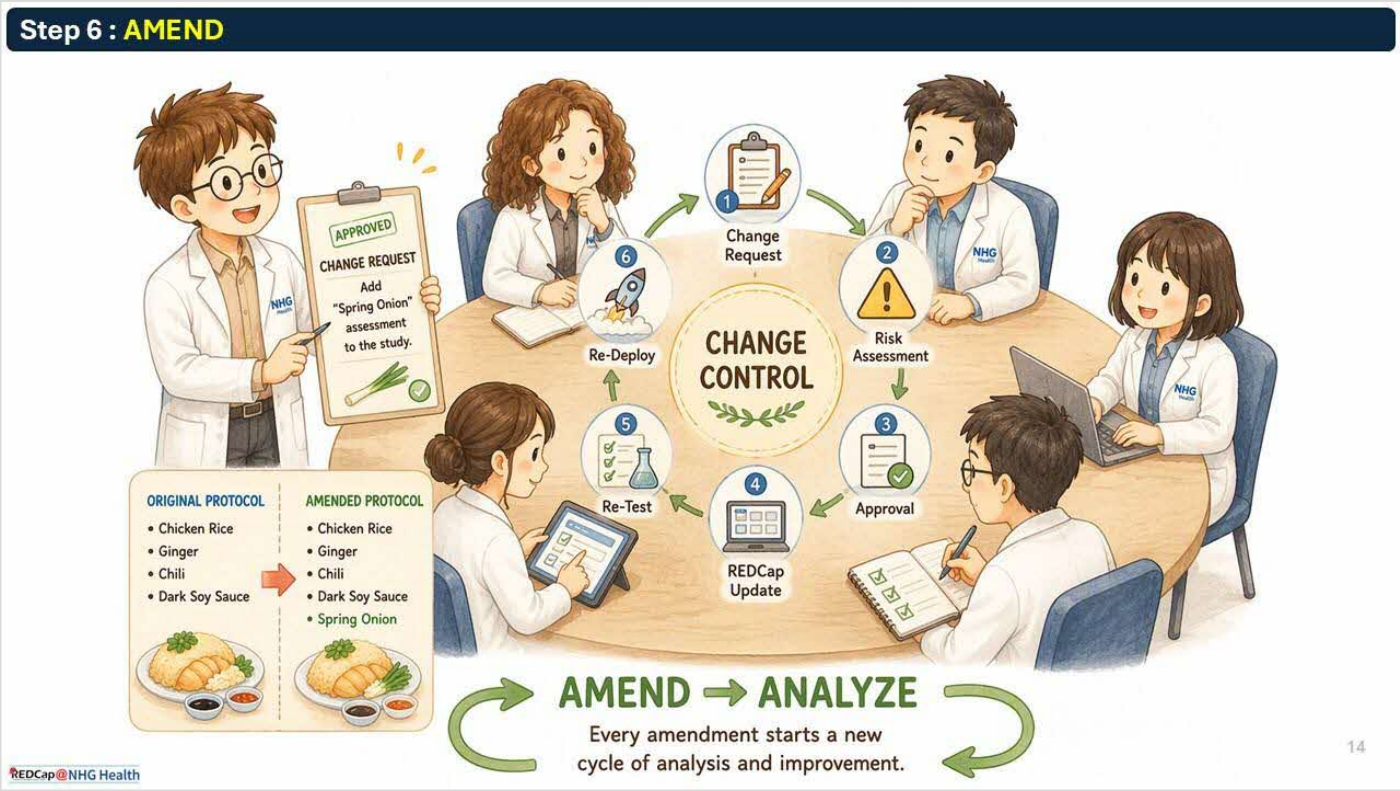
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**Step 5: Review – A Periodic Health Check for the Project**

- Study teams should periodically review how effectively the project is supporting study operations.
- Reviews may include user feedback, observations from data management activities, workflow assessments, or discussions regarding future study requirements. Are there recurring data entry issues, inefficiencies, or protocol changes that affect the project or its data?
- The objective is to determine whether the REDCap project continues to be fit for purpose.
- An important distinction should be noted — during the Review phase, no changes are actually implemented.
- Instead, potential improvements and changes are identified, discussed, and evaluated before any decisions are made.
- The Review step ensures that project changes are driven by genuine study needs rather than ad-hoc requests.

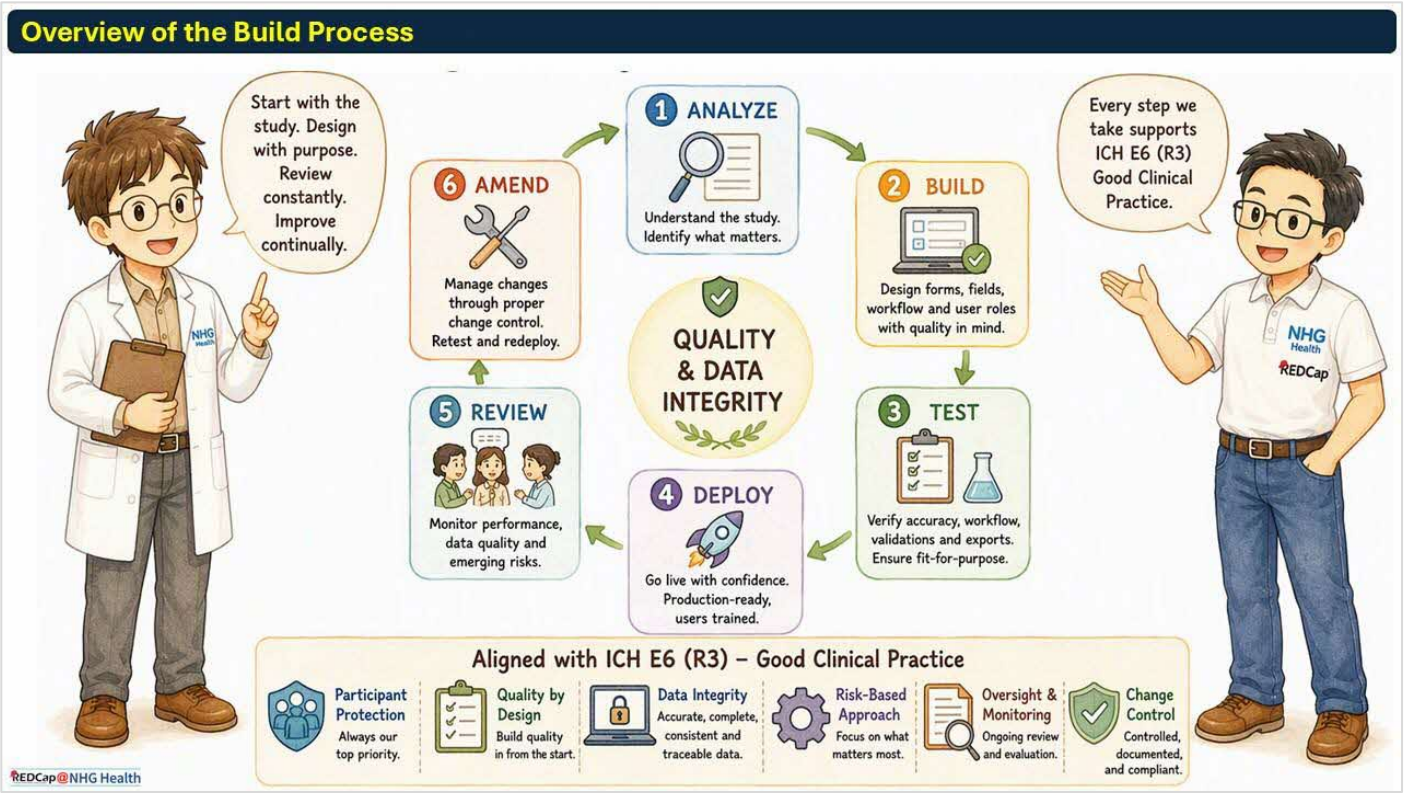
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**Step 6: Amend – Conducting change control**

- If the Review confirms a need for change, the project moves to the Amend step.
- The Amend step is about Change Control — not the actual implementation of changes to the REDCap project.
- Every amendment starts a new cycle beginning from Step 1 – Analyse.
- The study team follows the same process from Step 1, this time focusing on the proposed changes and their impact on the existing project and data, before working through the remaining steps to deploy those changes.
- In practice, this means analysing the impact of the change, building it properly, and testing it again. Once it passes testing, the changes are deployed into the REDCap project.
- This is how a REDCap project maintains GCP compliance throughout the life of the study — not just at the start.

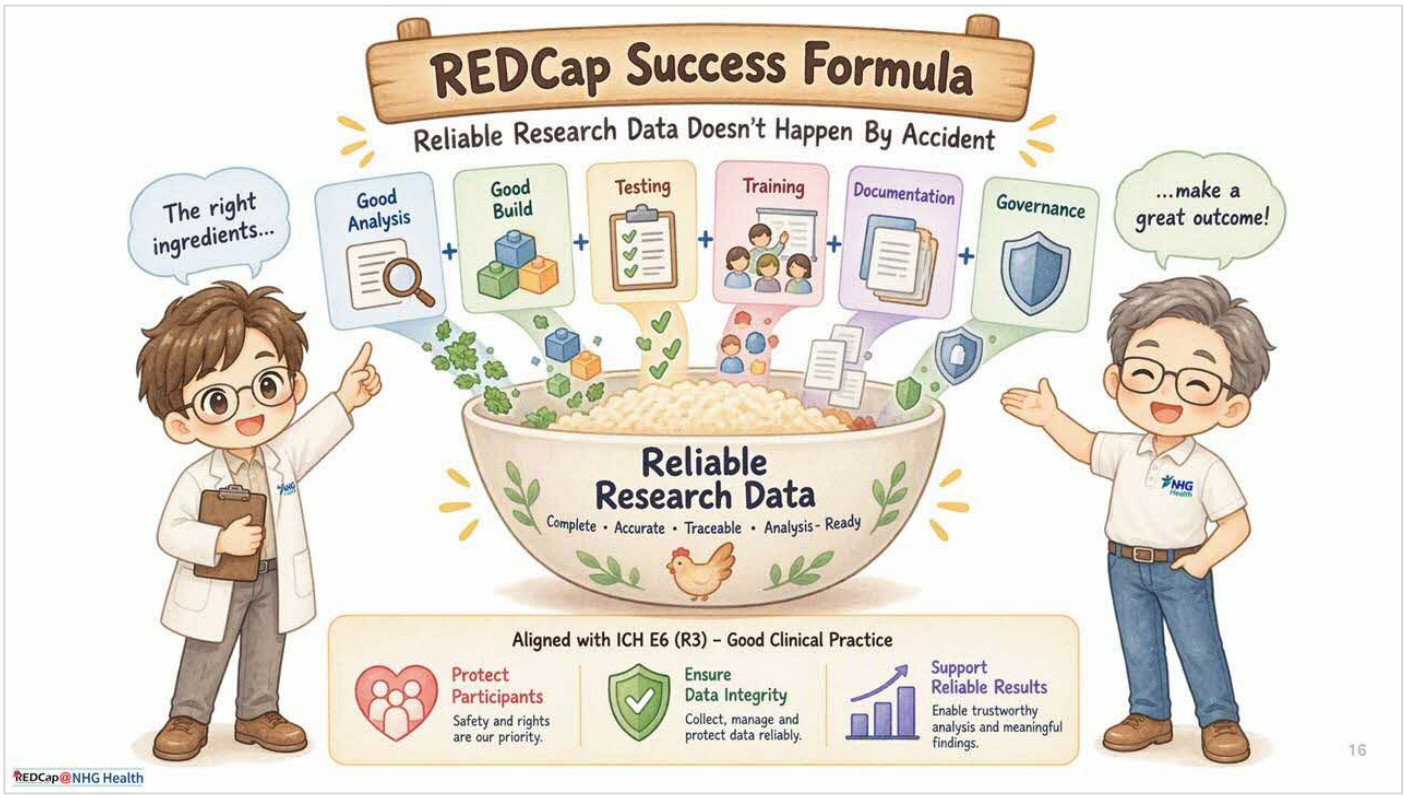
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**Summary**

- This slide provides a summary of the complete project lifecycle discussed throughout the presentation.
- Analysis helps establish clear requirements.
- Building translates those requirements into a functional project.
- Testing confirms that the project works as expected.
- Training prepares users for deployment, while Review and Amendment support ongoing improvement.
- Each step contributes to overall project quality and is aligned with GCP principles:
  - Participant protection is always the top priority.
  - Quality is built in from the start, by design.
  - Data must be accurate, complete, consistent, and traceable.
- At each step, the approach is risk-based — focusing on what matters most.
- When viewed individually, each step appears relatively simple. Combined, however, the six steps provide a comprehensive approach to managing REDCap projects in a consistent and structured manner.

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**Conclusion**

- This presentation concludes by emphasising that successful REDCap projects are not the result of any single feature, role, or activity.
- Project success is usually the result of multiple factors working together.
- Good planning, thoughtful project design, appropriate user access, thorough testing, effective training, and ongoing maintenance each make an important contribution.
- Balanced attention across all stages of the project lifecycle typically delivers the best outcomes.

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