# A paperless approach to clinical trial systems: from specification to validation, and beyond.

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## Introduction

Over the past decade, it has been widely accepted that a paperless approach to certain aspects of clinical trials can increase quality, efficiency and, in many cases, reduce risk. Handling large amounts of clinical trial data on paper can become very expensive, difficult to maintain, and has been linked to a higher rate of data errors and omissions.

Tangible improvements can be made to studies when they are designed with modern technology in mind. For example, participant diversity and inclusion can be increased or the time and mon­­ey spent on the collection, management, and validation of clinical trial data reduced.

Computer system validation (CSV) is the documentation and proof that a process, service, or product yields an expected result. It is an important part of the development and testing of computer systems within clinical trials and applies not only to specialist eSystem vendors, but also to Clinical Trials Units (CTUs).

Can a paperless approach to CSV further improve both quality and efficiency, while also satisfying the regulatory requirement to be always ‘inspection ready’?

## Methods/Approach

When designing clinical trial management and data capture systems there can be an immense resource overhead. A user requirement specification is created from a protocol, which is then developed into a computer system. However, before any computer system can be implemented for use in a clinical trial, an appropriate level of CSV is required. CSV ensures all systems meet the approved specification, adhere to the CTU’s standard operating procedures and good clinical practice (GCP), ultimately producing reliable data.

We provide a case study of a randomised control trial (non-regulated) where bespoke clinical trial management software is integrated with a third-party electronic data capture solution, REDCap Cloud. We discuss the **application and implementation** of the procedures put in place to minimise paper sign-off on specification, testing and validation documents. We consider the ability of version control software, cloud computing environments and automated build/deployment pipelines to aid in meeting regulatory GCP guidelines.

## Discussion

By replacing historically paper-centric tasks in our CSV processes we have seen a visible improvement in the efficiency of system development. We have strengthened the traceability of task execution and have a higher degree of confidence in the approval steps required across a system’s development. The remaining challenge we face is to ensure regulatory inspectors have a means of accessing electronic records at inspection, either via designated user accounts or tailored reports.