TRUSTING THE MIGRATION OF ACTIVE STUDY DATA

THE BUSINESS CASE FOR AUTOMATED MIGRATION VERIFICATION HAS NEVER BEEN STRONGER

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A NEW RISK PROFILE

The client, a Top 20 Biopharma pioneer, saw compelling benefits in switching to a new Electronic Data Capture (EDC) platform for a range of clinical trials. However, migrating active clinical study data demanded a fresh examination of the risks involved in this new arena.

All stakeholders and ultimately health authorities required assurance that the project would not compromise GxP data integrity or disrupt the progress of ongoing clinical trials. The project team turned to NNIT for clinical data management expertise and advanced data migration verification capabilities.

THE CHALLENGE

Previously, life science data migration projects have been document-centric, tactical projects centered around moving data from one single system to another. Today, migrations are data-centric, enterprise projects that support strategic transformation and enable new ways of working.

This means that migrating critical life science data is now more challenging, with increased risk, more complexity and greater expectation. Quality and accuracy are critical, and life science companies must get this right.

Our client was keenly aware that the new arena of active clinical data migration represented a further evolution of the risks and challenges involved, including the six listed to the right.

1. **Preserving data integrity and traceability:**
   Data integrity principles require justification and traceability for every single clinical data transformation necessary to allow study transfer to the target.

2. **Avoiding clinical trial delays:**
   The migration and verification project needed to align with strict clinical trial schedules, synchronized Standard Operating Procedure (SOP) releases and Clinical Research Associate (CRA) training which demand high levels of predictability for each study migration.

3. **Managing overlapping processes:**
   There is significant overlap between active clinical data management processes - standard data cleaning, discrepancy management etc. - and data migration activities. It was critical to recognize this overlap to ensure an accurate and precise accounting for live study issues.

4. **Double data verification:**
   The project scope included both active clinical data and configuration data (for study build). NNIT's teams needed to apply the same automated verification rigour to both.

5. **Minimizing down-stream impact:**
   The migration involved several critical down-stream processes like study listings and Study Data Tabulation Model (SDTM) outputs. The project team needed to ensure that the effort to verify these processes was minimized.

6. **Providing a clear audit trail:**
   As a novel undertaking, it was essential to ensure an end-to-end validation process that would stand up to the highest levels of Health Authority scrutiny.

NNIT'S SOLUTION

Working hand in hand with both our partners and the client, NNIT drew upon our vast experience with clinical data management to develop a validation and independent verification approach for each active study migration. This enabled us to provide the necessary data integrity assurance and project predictability in this new arena.

Using NNIT's proprietary TRUcompare software, we performed 100% automated verification of each data point. This enabled data migration issues to be identified early in test cycles and reduced potential disruption to busy study teams.

By combining NNIT's deep clinical data management experience and industry leading data migration verification capabilities, we ensured delivery of trusted clinical trial data at scale with 100% verification that source and target study data matched.

THE RESULTS

NNIT's clinical data management experience, data migration experience and proprietary TRUseries verification software enabled the client to proceed to a single new EDC platform with confidence that critical data risks were managed effectively. The complex alternative of supporting twin EDC systems in parallel (two sets of integrations, two sets of training etc) for new and existing studies was avoided.

Crucially, automated independent verification helped ensure that unintended bias was not introduced during the study data transfer process.
Ultimately, we applied a faster, repeatable, predictable, and traceable migration verification process to an enterprise portfolio of active studies.

Do you want to migrate active clinical trial data?
Please contact NNIT at nnit@nnitcontact.com to learn more.

The NNIT Migration Powerhouse – less risk, greater predictability, more opportunity. We don't just migrate, we innovate.

We make a mark

About NNIT

We are an international digital consultancy specializing in life sciences and the public sector. Our team of leading industry subject-matter experts and technology consultants help you empower those who change lives – and make a mark.

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