

# ARTICLE

BY NIELS BUCH LEANDER AND PHILIP PULS

NNIT is one of Europe's leading consultancies in the development, implementation, validation and operation of IT for the life sciences industry.

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## Why Use a Clinical Data Warehouse?

**Because of an increasing pressure to get products to market, there are four challenges that mean more data must be handled within a shorter time span:**

1. There is an almost explosive growth in data resulting from clinical trials: more trials are conducted, each trial collects more data and trial designs have become more complex.
2. Companies as well regulatory agencies are moving towards highly standardized study reporting and data exchange such as SDTM (Study Data Tabulation Model) — and this becomes more challenging as data volumes grow.
3. Adaptive business models are indispensable when traditional pharmaceutical companies outsource much of the clinical operation and statistical analysis, and data need to be exchanged quickly in a structured and uniform manner.
4. Many companies take over new products or late stage development projects, which then have to be transferred quickly into the company's systems in order to secure the continuation of the clinical development plan.

These challenges greatly intensify the pressure on the departments dealing with data management and statistics, departments that are already struggling to keep up with the workload and that often become bottlenecks in the release of the study data for any further usage. Consequently, valuable information may be unavailable and the pharmaceutical company loses time, money and opportunities — and may even face regulatory interference.

A clear solution to these challenges is a clinical data warehouse (CDW).

### THE VALUE PROPOSITION OF STANDARDIZATION

CDW's central benefit is that everyone can access the same data in near-real time. This benefit cannot be underestimated. For instance,

when biostatisticians, statistical programmers, bio-modelers and pharmacokineticians have access to a statistical computing environment, including a standard program library, they can focus on data analysis, as they are supposed to, not on programming. And when people involved in medical writing, pharmacovigilance and data management have access to a patient browser, they can focus on information analysis, as they are supposed to, and not on discussions about data interpretations arising from discrepancies and lack of standards. Moreover, when medical writers, trial managers, health economists and epidemiologists can perform ad hoc analysis across trials, they can focus on future trial design, cost savings and adaptation of running trials, as they are supposed to, instead of blindly repeating past mistakes.

### CDW ALLOWS FOR A CROSS-ORGANIZATIONAL FOCUS

By being first and foremost a drive towards standardization, a CDW presents the pharmaceutical company with the following benefits:

- better use of internal resources
- reduction in critical time path for statistical analysis
- standard exchange of data with CROs, partners and regulatory agencies
- cross-trial analysis and leveraged use of historical data
- globalization and knowledge sharing
- compliance with regulations.

### HOW TO IMPLEMENT A CDW

However, the implementation of a CDW is an immense undertaking. It will undoubtedly involve a number of key resources in the company, which may put further pressure on an already strained organization. If the CDW is to be delivered successfully and on time, it is therefore crucial to rely on a number of pre-designed solutions as well as an implementation partner with a clear design methodology and a proven track record of implementation projects.

In the early stages of the CDW design, it is important to focus on the business process



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## ABOUT THE WRITERS

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and not on IT. Yet, since a CDW is essentially a drive towards standardization, it is vital that the standardization process be commenced as early as possible.

The key to a successful implementation of a CDW is to use a common IT Project Management Model with a focus on IT governance as well as a strong, dedicated steering group. The project management group must consist of a senior business project manager and project manager who is responsible for the IT solution. The project team should be heavily represented by biostatisticians and statistical programmers, as well as subject matter experts from the software vendor and implementation partner. Finally, it is important to have adequate representation from the quality department.

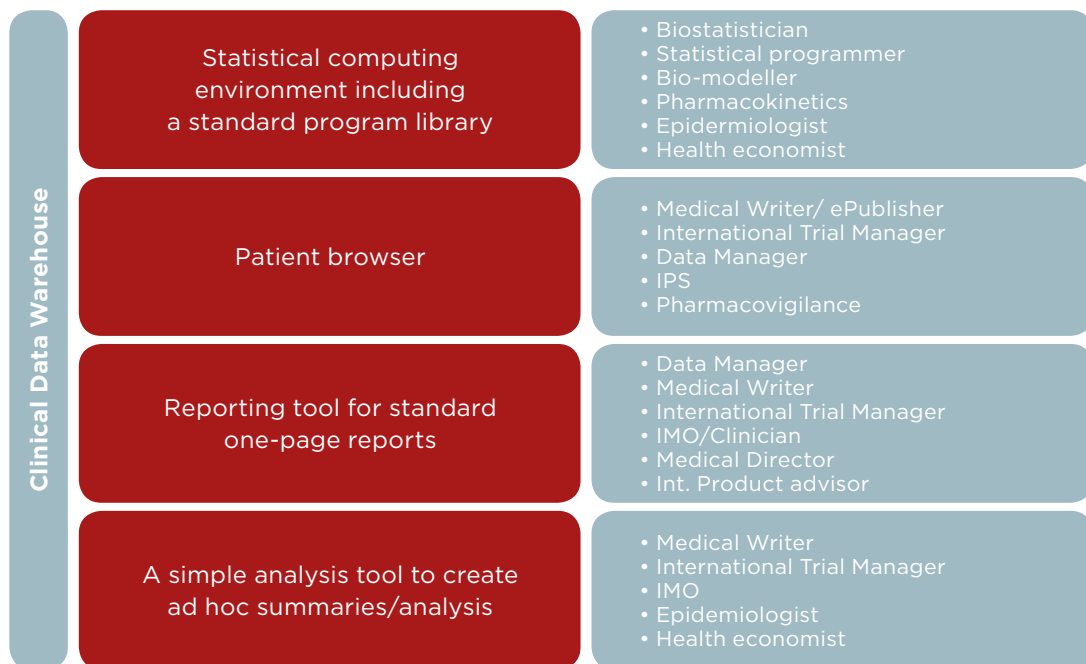
It is advantageous to break up the project into smaller releases that individually provide benefits to the company. This approach secures user participation and allows users to provide feedback that can be used to adjust the design of future releases.

The objective of the CDW is typically to become the source of the statistical analysis and the

foundation upon which to automate the analysis and reporting that are part of a submission. As a result, the CDW has a potential impact on the final product and should be rated critical in terms of GCP. Consequently, the system has to be implemented in compliance with GAMP and ICH and 21 CFR Part 11.

As there are few off-the-shelf systems available that offer the full solution, it is to be expected that some company specific adaptation is needed, especially in relation to data load and metadata management solutions. This, however, increases both the validation effort and the complexity, thereby raising the project risk profile. In order to mitigate risks and reduce validation efforts, it is crucial to select an implementation partner with a set of accelerators upon which the system can be based. The accelerators should facilitate reduction in system specification, design, construction and test of the CDW modules.

The benefits of a CDW are obvious. Yet, since the implementation is both complex and demanding, the CDW only lives up to its full business potential if based on a solid design that both supports the drive towards standardization and eases the implementation.



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