Document management systems for medical writing

Brendan Thorne
ICON Plc., Dublin, Ireland

Correspondence to:

Brendan Thorne, BSc (Hons).
ICON Clinical Research UK Ltd
6 Stoneycroft Rise
Chandlers Ford
Eastleigh, Hampshire SO53 3LD
United Kingdom
+4423 8068 8529
Brendan.Thorne@iconplc.com

Abstract

Clinical trial data are rightfully protected by robust regulations; given these requirements and increasing demands from clients, a validated and compliant electronic document management system is now a necessity for established medical writing organisations and contract research organisations. Even without this impetus, the improvements in administrative function, audit readiness, and team collaboration can justify the investment required.

Introduction

In a world where data security is increasingly under the spotlight; the old order of manually tracking file names with ever-increasing dates or versions on a file-share or drive is unlikely to meet client or auditor requirements moving forwards. This article provides an overview of the benefits and challenges observed after the implementation of an electronic document management system (eDMS) within the medical writing department of a large contract research organisation (CRO).

> In a world where data security is increasingly under the spotlight; the old order of manually tracking file names with ever-increasing dates or versions on a file-share or drive is unlikely to meet client or auditor requirements moving forwards.

Background

ICON Medical Writing, in partnership with our vendor, implemented a cloud-based document management system using the Software as a Service (SaaS) model. This system was first installed in 2015. The goal was to comply with the FDA Code of Federal Regulations (CFR) Part 111 and EMA Good Manufacturing Practice (GMP) Annex 11 guidelines,[2] and to respond to the increasing document security requirements of clients.

Regulatory need

The FDA and EMA guidance set a high bar for the storage and tracking of electronic documents related to clinical trials. The FDA's 21 CFR part 11 requires that systems are validated, secure, auditable, and that records are stored and retained as accurate and complete copies in readable and electronic formats. It also specifies that compliant systems will support electronic signatures and limit system access to only authorised individuals.[1,3] The EMA's GMP Annex 11 was revised in 2011 in response to the increased use of computerised systems and their increasing complexity. While many of the Annex 11 requirements and principles are similar to those included in 21 CFR part 11 (audit trails, electronic signature, document security), Annex 11 goes into additional detail around the use of third-party suppliers, the qualifications of IT infrastructure and the validation project phase.[2]

Document management systems have long been established within large pharma but there is increasing scrutiny to ensure that CROs also store working copies of their trial documentation to these standards. This is especially true for documents containing any protected personal data that may reveal sensitive medical information or the identities of trial participants, or confidential proprietary information, both of which are commonly found in documents authored by medical writers.

Implementation

Configuration

From our experience, it is highly unlikely that there will be complete alignment between the out-of-the-box configuration of the chosen system and the processes that are in place within your medical writing organisation. During implementation, it will be key to identify where the stock system configuration should be modified to fit in with these procedures and *vice versa*. It is important to maintain a long-term view; the essence of a procedure must be maintained but any system configuration changes that attempt to mimic previously manual procedures may result in imperfect compromises that negate the benefits of automation.

It is important to have intensive testing prior to implementation that includes input from writers with a variety of roles and experience levels. We found that helped to identify where the system configuration and processes could be better adapted to fit with our department's way of working.

Training

A well-executed training programme is essential for the smooth introduction of a new eDMS into a medical writing department or organisation.

A combination of instructor-led training and detailed reference materials will give users the confidence needed to embrace the new system. The vendor providing the system is usually best placed to provide this training.

A successful training programme will teach writers how to work with the new system according to their previous writing preferences whilst maintaining compliance with the new procedures that govern the system. Establishing confidence in the system will prevent new users from reverting to legacy systems. The availability of these legacy systems may create a disincentive for users to fully buy-in to a new way of working so there would be benefits in ensuring assess to these is revoked as early as practical.

Evolution

It is important to adapt and improve the configuration of the eDMS as the project matures. A critical challenge to the use of eDMS in a large CRO is the maintenance of inter-sponsor security when providing clients with access to their documents.

In our initial system configuration, this was achieved by storing each sponsor's documents in a separate sponsor-specific environment. This was very effective at maintaining security as new users needed to be provided with direct access to a sponsor's environment to see any of their documents; however, each new environment directly increased the level of administrative and technical support that was required.

In response to this, and after new functionality became available, the vendor and ICON redesigned the system configuration so that all documents could be stored in a single environment. This new environment utilises dynamic security that prevents sponsor users gaining access to the documents of another sponsor. A large revalidation and testing programme was performed to confirm the integrity of these

security measures before the new system went live. These changes generated beneficial reductions in administration time and an increase in general engagement as users now had all of their documents within a single location. With a true SaaS model and new innovations delivered on a scheduled basis, there are continual opportunities to improve processes.

Benefits

Collaboration
Automated workflows can track quality control (QC) reviews, capture the details of all QC participants, and allow for electronic signature. A record of all reviews is kept on the system; reports and audit trails can be exported from the system, if required. The introduction of workflows has allowed ICON Medical Writing to phase-out the use of hard copy QC forms, reducing the administrative burden associated with project filing. A significant advantage in the area of collaboration also comes from the very nature of SaaS solutions compared with legacy on-premise systems. It is easy to externalise and involve the sponsor organisations in the actual review process, leading to fewer review cycles with documents.

Pick up and play
One benefit from moving to an eDMS has been an improved ability to quickly start work on a new project. Detailed meta-data link documents to specific projects, clients or a therapeutic area, which improves the ability of a writer to step into a project and identify and work with the required documents with no loss of continuity. Automatic version management functionality and associated workflows provide easy access to all incremental document versions and a quick overview of their place in that document's development.

This is a significant step-up from a manual file system as even when writers are diligent and standardised structures are in place, an absence of project knowledge can make it hard to quickly get up to speed on a new assignment.

Inspection readiness
The implementation of an eDMS and robust processes around this can notably reduce the preparation time, compliance risk and stress around an upcoming client audit or regulatory inspection.

Replacing paper QC forms with review workflows removes the risk of missing signatures as the system will require the reviewer's electronic signature before completion; comments can also be stored and responded to within the system. The version control ensures that all major and minor versions are clearly tracked and can be identified and provided to auditors, if requested. These systems also give users the ability to export an audit trail that details all actions taken with a document.

This increased visibility of the document development process provides auditors and regulators with confidence in the completeness of the data presented to them and reduces the overall time and effort associated with an audit.

Challenges

Rigidity
The validation process that is essential for regulatory compliance can also provide challenges. Some of the flexibility afforded by manual systems has to be relinquished when working within the structure of a validated system. Configuration changes can take longer to implement because of the need to update specification documents and conduct formal testing.

Organisations without an in-house validation department may want to consider their approach for maintaining their chosen system's validation and regulatory compliance when changes are required to the configuration. This will assist in keeping the system current and allow for adaptation as their needs change. However, it should be recognised that SaaS solutions come with the advantage that the system owners no longer need to invest significant efforts in the lower levels of validation such as Installation and Operational Qualification that were traditionally associated with on-premise systems.

Managing change
Any large-scale change to the daily workings of an organisation will present challenges; medical writers are certainly not immune to this. The importance of fine-tuning the initial configuration and a well-planned training programme have been discussed; these will ease the transition, but it is also important to understand that writers will take time to adapt to the new system and additional support may be needed. An important part of this process is the communication of a well-defined plan for transitioning work to the new system. With the support of the vendor, this can be further simplified through the use of their expertise in delivering materials to support your change management approach.

Conclusion
A validated and 21 CFR part 11- and Annex 11-compliant eDMS is now a necessity for established medical writing organisations and CROs. Even without the impetus from clients, the improvements in administrative function, audit readiness, and collaboration can justify the investment required.

Disclaimers
The opinions expressed in this article are the author's own and not necessarily shared by ICON Plc or EMWA. This article has been written independently of ICON Medical Writing's eDMS vendor; however, the vendor was given an opportunity to review and provide comments.

Conflicts of interest
The author is employed by ICON Plc.

References
1. FDA, CFR - Code of Federal Regulations Title 21, Volume 1. Revised: 01 April 2018 [cited 2019 April 26]. Available from: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=11.
2. Article 47 of European Commission Directive 2001/83/EC. Volume 4 Good Manufacturing Practice Medicinal Products for Human and Veterinary Use. Annex 11: Computerised Systems.
   [cited 2019 April 26]. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-4/annex11_01–2011_en.pdf.
3. FDA Guidance for Industry Part 11, Electronic Records; Electronic Signatures – Scope and Application.
   [cited 2019 April 26]. Available from: https://www.fda.gov/downloads/Regulatory Information/Guidances/ucm125125.pdf.

Author information
Brendan Thorne has been a medical writer at ICON Plc since 2010 and is the business lead for the eDMS. Brendan gave a presentation entitled "Collaborating in the Cloud – A New Way of Working with Clients" to the 2016 Vendor European R&D Forum in Copenhagen.