Publication management software for medical writers

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Abstract

Managing a complex publication plan for several products or indications with overlapping timelines can be challenging. Publication management software solutions are available to support the medical writer in planning, writing, approving, and disseminating scientific publications. Key features of these programs include design and approval of a publication plan, verification of author eligibility, assignment of medical writing resources and authors, management of document reviews, auditing of author contributions, and ensuring compliance with industry standards, transparency requirements, and standard operating procedures. Some software packages provide data visualisation tools to track performance, budget spent, and author engagement. Medical writers supporting publications should become familiar with software features to improve efficiency in managing and writing scientific communications.

The pharmaceutical industry is committed to publishing clinical study results, irrespective of whether they are positive or negative.[1] By disseminating scientific data, as abstracts, posters, presentations, or manuscripts, pharmaceutical companies meet ethical guidelines, industry standards, and corporate compliance requirements.[2, 3]

Publication planning

A publication plan is a product-specific strategic document that evolves over a product's lifecycle according to the stage of research. It is generally developed and executed by the medical affairs department in collaboration with cross-functional stakeholders. The publication plan specifies how the communication will be delivered (e.g., poster, manuscript, presentation, or video content), what audience will be targeted (e.g. payer, healthcare provider, patient), what the content will be, and what the strategic messages will be. Key messages may be defined according to the research conducted, competitor analysis, or gaps in published literature. Deciding where to present research can depend on the type of research conducted, the audience to be targeted, the type of publication, and journal metrics (impact factor, publication lead times, and rejection rate).[4]

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In addition to the well-established role of the medical writer in authoring content and managing reviews of publications, medical writers are often consulted to contribute to the strategic publication plan. However, managing a publication plan for multiple products or indications with overlapping timelines can be challenging. An integrated software solution can help design, approve, and implement a publication plan, verify author eligibility, assign resources and reviewers, manage document reviews, audit author contributions, and ensure compliance with Good Publication Practice guidelines, transparency requirements, and standard operating procedures.

In this article, I present key features of three proprietary software solutions designed to support company-sponsored publication plans (Table 1).

The PubSTRAT suite

The PubSTRAT suite (Anju Life Sciences Software) is an integrated software solution comprising several web-based applications covering publication planning, writing, document management, and citation. These solutions include JSCA (Journal Selector and Conferences Authority), SYQUENCE (an information life-cycle management platform), PubSTRAT (Publication Project Management Application), and Cite Central (a citation and knowledge repository). These individual platforms may be purchased separately or as a single integrated solution.

JSCA

JSCA, a journal and conference database that includes more than 2,500 journals and 1,500 conferences (and 600,000 abstracts), can be used to design a publication plan. Users can search the platform by MeSH (Medical Subject Heading) term and can access a list of journals, a citation count, journal impact factors, Eigenfactor scores, and journal selection criteria. Crucial information that assists in publication planning includes the estimated time from submission to acceptance and time from acceptance to publication. Selection criteria for conference acceptance are also included and are updated daily as the conference date approaches. Analytic features include the number of articles published by journal per topic/MeSH term within a given timeframe, which can be presented in both in tabular and graphical formats. Future updates will include an abstract library sourced from the JSCA database.

Table 1. Key features of publication management software

Feature	PubSTRAT	Datavision®	PubsHub™
Author publication management	X	X	X
Real-time review	X	X	X
Document audit trail and version history	X	X	X
Configurable email templates and notifications	X	X	
Journal and conference database	X	X	X
Publication planning software	X	X	
Project wizard	X	X	
Configurable timeline templates	X	X	
Data visualisation module	X	X	
Publication repository	X	X	X
Veeva Vault integration	X	X	X
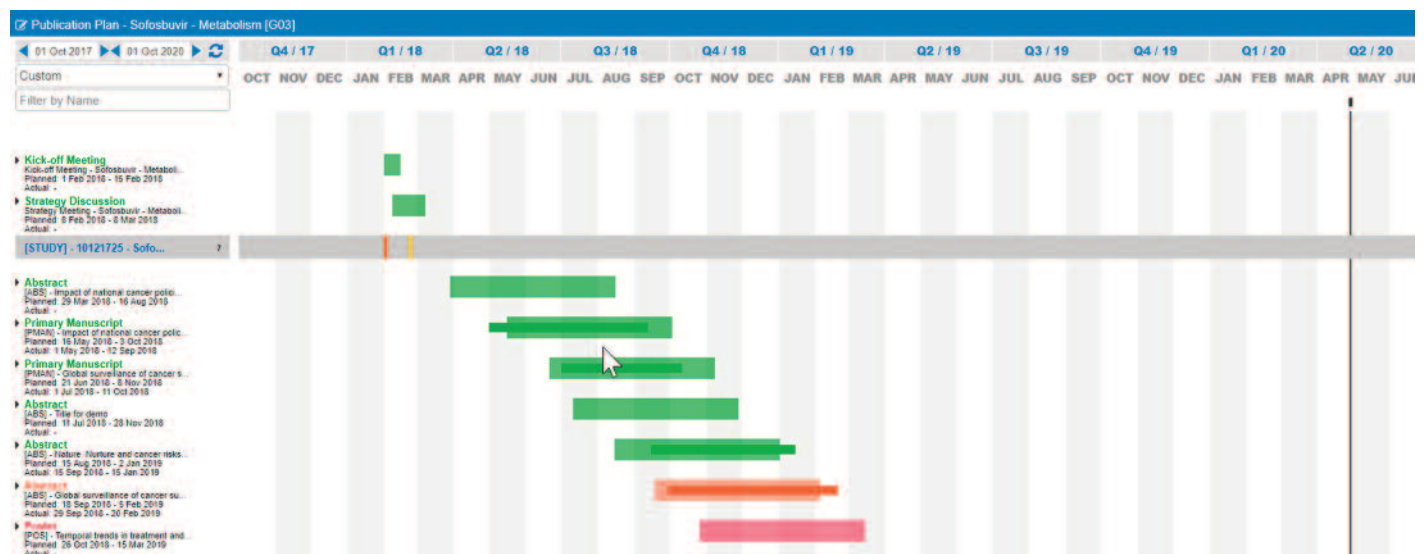
Figure 1. Publication plan Gantt chart: SYQUENCE (PubSTRAT)
In SYQUENCE, publications by project and type are presented vertically. The timeline for each project is shown horizontally on a Gantt chart by quarter, month, and year. The colour coding describes the project status: red indicates pending, orange indicates active authoring, and green indicates published. Projects can be filtered by project name or timeframe.

Figure 2. Publication management page: PubSTRAT

In the publication management page of PubSTRAT, tasks can be filtered by product, due date, or project. Projects can also be accessed by status on separate tabs ("To Do", "Planned", and "Done"). By clicking the task, users can view this task in the overall timeline. By clicking the project name, users can view project details shown in the project page. By clicking on the icon in the Actions column, users can delegate a task to a specific person.

SYQUENCE

The SYQUENCE application enables users to create the publication plan in an electronic format and to circulate it for approval by a steering committee or leadership. SYQUENCE captures tactics (strategic recommendations) for a study or product, including the focus of communication, the target audience, and key dates and milestones. This allows for publication tactics to be mapped on a timeline (Figure 1). Once the plan is approved in SYQUENCE, each tactic is automatically synched with PubSTRAT as a separate project.

PubSTRAT

PubSTRAT integrates publication planning and workflow management for internal and external authors through a cloud-based application. System access can be configured by user type (e.g., project manager, medical writer, or reviewer). Users can create and manage projects in PubSTRAT and assign tasks for project contributors to execute. Details of the scope and audience for each journal or congress targeted in the publication plan are hyperlinked in PubSTRAT.

PubSTRAT provides templates for generating author invitations, author agreements, and electronic checklists for meeting authorship requirements, and it can capture digital signatures.

As such, PubSTRAT can be used to audit author engagement and demonstrate compliance with Good Publication Practice guidelines and corporate integrity agreements.

Publications can be viewed from a publication management page (Figure 2). Further details for each publication, including the target journal, lead author, corresponding author, assigned medical writer, and active tasks, can be viewed from a project page. Managers can assign medical writers to a project, which will trigger an automated email to the writer. Workflows are created according to the timelines allocated in configurable project timeline templates, which include document development, review, and approval steps. Workflow subtasks may be delegated to other authors or reviewers. Additionally, based on the timelines in the workflows, automated reminder messages for authors are triggered. The platform allows for online document writing, simultaneous document review, and approval by internal and external authors. PubSTRAT includes suggested timelines by deliverable (e.g., abstract, poster, manuscript), which can be configured to meet the client needs.

To help oversee the publication process, data visualisation tools are available, including performance metrics (e.g., publications accepted, cancelled, in progress, pending finalisation, and rejected) and budgeting tools (e.g. budget spent and remaining).

CITE CENTRAL

CITE CENTRAL is a centralised web-based repository for citation information and final documentation for documents created in PubSTRAT. It creates automatic citations and consolidates a product bibliography, and it can be used to disseminate publications to internal and external stakeholders.
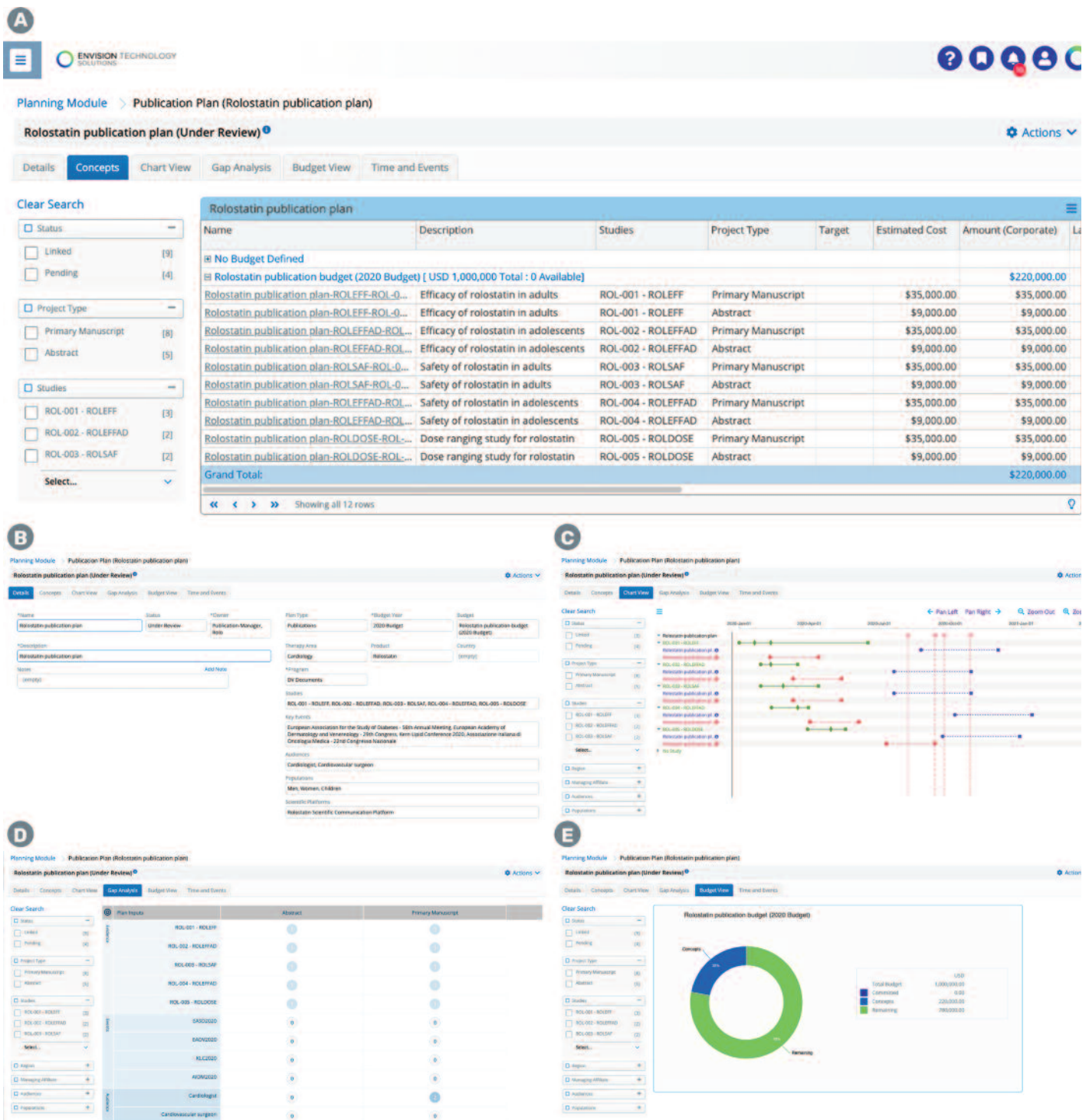
Datavision®

Datavision (Envision) is a web-based software platform that integrates a journal and congress database of over 7,000 journals and 27,000 congresses, a publication planning module, a document management system, and a scientific communication platform.

Scientific communication platform

The scientific communication platform allows companies to load themes, key communication points, and supporting statements into the system and then visualise how the publications align with the publication plans. Optional features that may be purchased separately include an enterprise content management library that allows publications to be captured, managed, archived, and distributed; finance and budgeting

Figure 3. Publication plan: Datavision

A. The Concepts tab of the publication plan shows a list of planned projects included in the publication plan.

B. The Details tab, which provides the studies and other inputs upon which the publication plan is based.

C. The Chart View tab shows a Gantt chart of projects included in the publication plan.

D. The Gap Analysis view provides the planned publications by audience and tactic versus the plan's inputs; for example, the input for the congress EASD2020 shows that no abstracts are planned (indicated by the circle with an embedded zero).

E. The Budget view shows the allocated budget vs. budget spent by project.
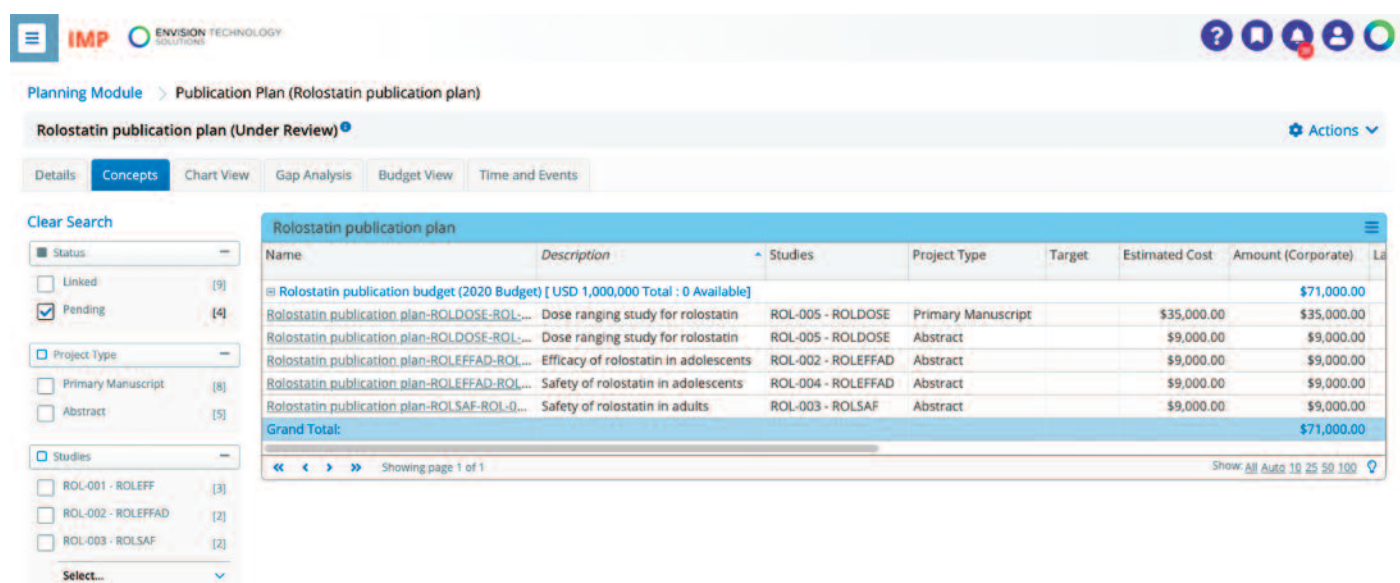
Figure 4. Publication Plan Concepts list: Datavision
The Publication Plan Concepts list in Datavision includes a summary list of concepts (also known as tactics or strategic recommendations) included within the publication plan. Users can click the hyperlinked project name to retrieve further details of the study included in each project, such as the first subject first visit, last subject last visit, publication type and audience, project timelines, and linked statements about the data to be relayed to appropriate external audiences.

tools; automated healthcare provider debarment checks; and an enhanced scientific communication platform.

Publication planning module
In the publication planning module, a wizard can be used to design a publication plan that specifies tactics; audiences, journals, and congresses; and potential differences between the plan and the communication objectives (Figure 3). The module provides metrics from the journal and congress database, including the overall acceptance rate, the size and nature of their audience, and, for journals, the impact factor, Eigenfactor score, and types of articles published. A consolidated publication plan can be viewed from a summary list. (Figure 4).

The publication plan can be circulated, reviewed, and approved in Datavision. Datavision converts the details of the publication plan into a PDF for review and approval. Reviewers will receive a notification that includes a link to the publication plan review. They can comment on the publication plan using embedded review software. Comments are stored in Datavision. Once it is approved, based on the type of communication (e.g., abstract, poster, manuscript, presentation) and submission deadline, the platform will generate a proposed

timeline that may be viewed from a project management page (Figure 5). Since Datavision integrates with clinical trial management systems that capture study timelines, Datavision can be used to highlight the required changes to milestones in the publication plan if study dates change.

Internal and external authors may be assigned to a project in Datavision. Author permissions, including the reports and dashboards they have access to, are configurable. Electronic signatures (through DocuSign®) and electronic capture of conflicts of interest and disclosures can be completed in Datavision. To confirm authorship eligibility, the platform also features an automated debarment check (i.e., proposed authors have been excluded, suspended, or otherwise ineligible to participate in Governmental health care programmes).

Managers can use the software to assign a medical writer, which will trigger an email to the writer. Medical writers will interact with Datavision via a workbench view, which is a consolidated list of assigned projects and current and future tasks to perform. Medical writers can manage author review and approval workflows from this page. Automated reminders are triggered according to predefined but configurable timelines. Supporting documents may be stored

for author access during review. By the third or fourth quarter of 2020, functionality for simultaneous review by multiple reviewers will be enabled using doDOC (doDOC.com), a real-time co-authoring tool.

To provide managers with oversight of the status of the publication, reporting tools are available for document review metrics and budget planning. An at-a-glance view of progress against the publication plan and project milestones is displayed on a Gantt chart. A dashboard view (Figure 6) provides high-level metrics by project, a document timeline, publication plan metrics, and a list of outstanding tasks. Reports can be configured, saved as templates, and exported. Additional analytic features for further data visualisation include integration with the data analytics platform QlikView® and the ability to export to other business analytics tools (e.g., SAP BusinessObjects, Tableau, and Sisense).

To enable company-wide or role-specific distribution, once publications are finalised, they can be pushed from Datavision into a document library or another third-party document repository (e.g., Veeva Vault), which can be used to store, manage, and distribute regulatory and clinical trial documentation. For each publication, a count of citations is displayed. The enterprise content management library can be

Figure 5. Project Management page: Datavision

In the Project Management page of Datavision, the project manager can manage each publication. The left side of the page shows (**A**) document details, including the target journal or congress, (**B**) the document version, (**C**) a link to supporting materials (e.g., tables, listings, literature references) to be used in review and quality control, (**D**) the author list, and (**E**) a link to the study in the study database. On the right side of the page, (**F**) the project plan is presented by timeline, and (**G**) timeline step. Using the Actions dropdown menu (**H**), the project plan milestones can be updated and the document can be sent for review and approval.

used to develop and distribute a bibliography of suggested reading materials.

PubsHub™

PubsHub (ICON) is web-based integrated publication planning solution comprising a database of medical journals and scientific congresses (Journals & Congresses), software for publication planning and management (PMSolution),

and a publication repository (Knowledge Manager). The software may be purchased as an integrated solution or as separate modules. A subscription to PMSolution includes access to Journals & Congresses.

Journals & Congresses

Journal & Congresses is a publication planning research engine that provides key data points for

over 4,600 journals, 3,500 congresses, and 4,000 professional scientific associations, spanning more than 100 medical and scientific therapeutic areas. Key metrics for journals and congresses can be compared (Figure 7). Content is updated on an ongoing basis. Predatory journals and congresses are flagged and excluded from the database. Information for journals includes the impact factor, circulation, readership, rejection

Figure 6. Publication Manager dashboard: Datavision
In the Publication Manager dashboard of Datavision, the left side of the dashboard provides (**A**) links to recent documents accessed, as well as outstanding tasks, (**B**) a project status summary, and (**C**) pie charts showing projects by type and status. On the right side of the dashboard, (**D**) project managers can include alerts or other general information to be viewed by Datavision users and (**E**) display summary metrics for publication status in a bar chart. In (**F**) a comparison of actual timelines (in dark green) and projected timelines (grey) is also presented.

Figure 7. *Journal Compare features (Journals & Congresses) PubsHub*
The Journals and Congresses database of PubsHub provides a comparative view of journal metrics key to publication planning, including rejection rate, impact factor, and circulation. Timelines from submission to print publication are colour coded as green for submission to acceptance, purple for acceptance to online publication, and blue for acceptance to print publication.

rate, submission timeframes, restrictions on "encore" publications, and submission guidelines. For congresses, deadlines and the availability of extensions are provided.

PMSolution
PMSolution is a software platform for project management and collaborative document review that provides an audit trail for author involvement. It has two modes of operation for document review: a traditional workflow and "CoAuthorLive".

In the traditional workflow, after initiating a review, reviewers receive an automated email containing a link to access the document. Reviewers can sequentially access, edit, and upload a revised copy of the document. Reminder emails to reviewers are manually triggered. CoAuthorLive allows real-time simultaneous review by multiple reviewers.

Key metrics (e.g., adherence to timelines by reviewers) are displayed on dashboards if meta-data are added to the document. A forthcoming update to the platform includes enhanced analytic capabilities and data visualisation.

Medical writers and project managers can access and view the current status of projects via a user-specific project dashboard (Figure 8). Security features are available to limit functionality and access by user type. To facilitate project creation, a "copy project" feature enables replication of project information, metadata, supporting documents, and team members. Lastly, PMSolution can track payments to authors.

PMSolution can be integrated with Veeva Vault and can thereby be used for management of document workflows. Once a document is approved, it can be pushed into the Vault PromoMats document repository, which enables automated distribution to internal and external stakeholders.

Knowledge Manager
Knowledge Manager is a document repository for published copies of publications that can be integrated with PMSolution. It can be used to search for publications and distribute them to internal and external stakeholders. Supporting information for users, such as documents supporting the rationale and key messages for the publication, can be added. Content can be searched based on tagged metadata that are manually entered.

Conclusions
Medical writers supporting scientific publications can enhance their productivity by using a comprehensive software solution that dovetails all aspects of publication management, from inception of a publication plan to final dissemination. Using a standardised software solution can assure a consistent process, reduce time spent managing the tasks in executing a publication plan, and ensure compliance with industry standards, transparency requirements, and standard operating procedures.
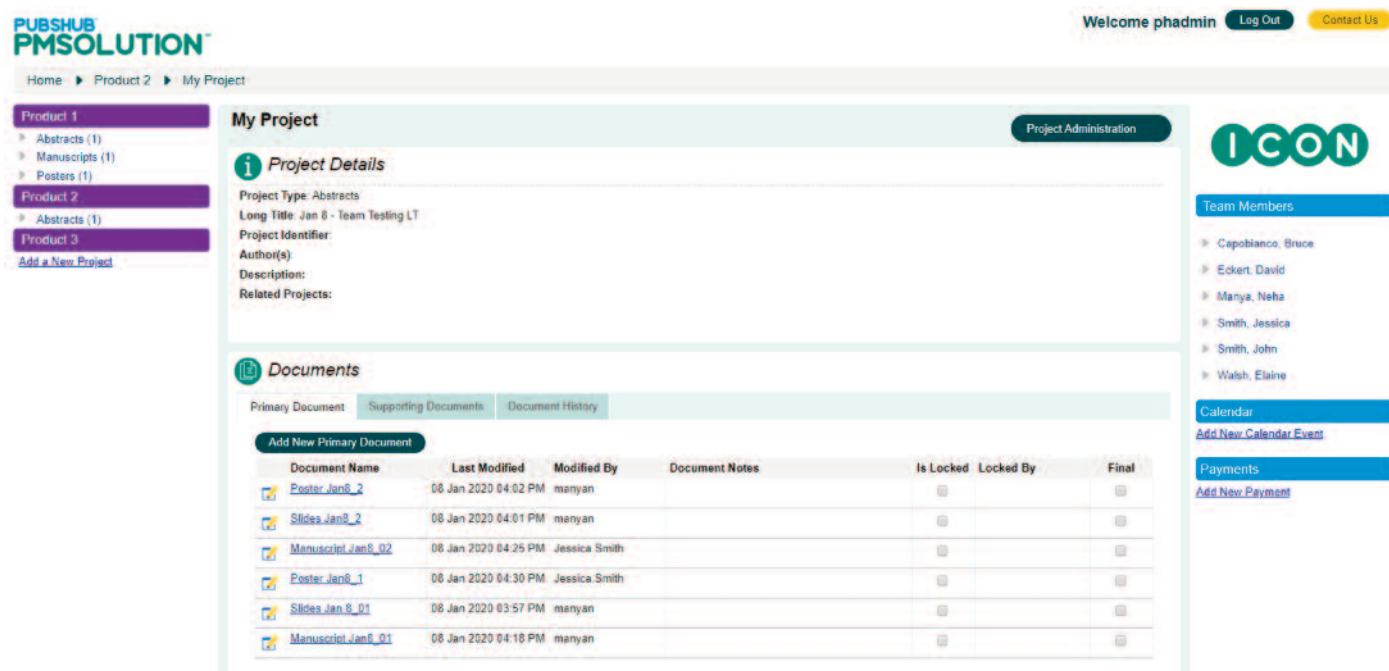
Figure 8. My Project dashboard page: PubsHub
From the Primary Document tab in PubsHub, project or product managers can access all publications in development. Revisions to publications can be uploaded into PubsHub from this page. From the Supporting Documents tab, users can upload sources used in review or quality control, and from the Document History tab, they can view versions and audit revisions.

While PubSTRAT, Datavision, and PubsHub include databases of journal and congress metrics to assist in publication planning, PubSTRAT and Datavision also include robust publication planning software packages with features that allow stakeholders to design, modify, and approve a publication plan. PubSTRAT and Datavision also include features to assist in executing the publication plan, including templates for invitation emails to authors, automated author eligibility checks, assignment of medical writing resources, and modifiable timeline templates. Datavision's integration with clinical trial management software allows for real-time updates in the publication management plan when study timelines change. Finally, Datavision's detailed dashboards allow managers to monitor the execution of the publication plan.

PubSTRAT, Datavision, and PubsHub support document review and approval, and all support simultaneous collaborative review rather than sequential review. They all include document repositories for published scientific communications that integrate with the Veeva Vault document management system. To further streamline the publication management, future iterations of publication management software should include integration with journal submission platforms.

Disclaimers

The opinions expressed in this article are the author's own and are not necessarily shared by her employer or EMWA.

Conflicts of interest

The author declares no conflicts of interest.

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