



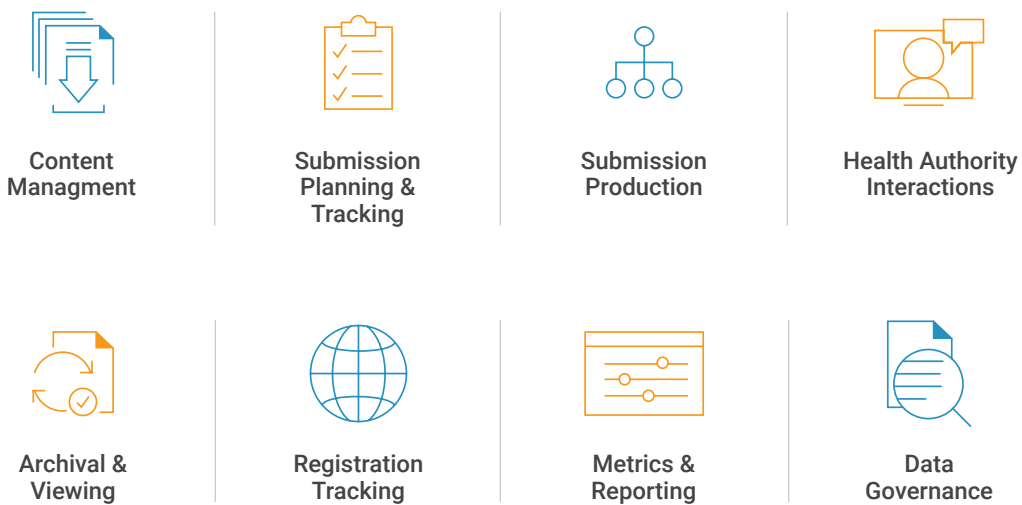
AgiOS Pharmaceuticals Actively Manages Health Authority Interactions with Veeva Vault RIM

After launching Veeva Vault Submissions and Vault Submissions Archive in late 2017, Agios Pharmaceuticals realized several system benefits like better document tracking through authoring workflows, automated reporting capabilities, and improved lifecycle management. To further streamline regulatory operations and improve information gathering, they turned to Veeva’s value consulting team.

AGIOS PHARMACEUTICALS – AT A GLANCE

- Corporate Headquarters: Cambridge, MA
- 500+ Employees
- Primary Therapeutic Area: Oncology and Rare Genetic Diseases

Veeva value consulting helps companies maximize the value of their investment in Vault applications by characterizing and quantifying the impact of process improvements. With Agios, the value consulting team conducted a maturity assessment that considered eight core RIM capabilities: content management, submission planning and tracking, submission production, health authority interactions, archival and viewing, registration tracking, metrics and reporting, and data governance. The maturity assessment included scores for both current and desired RIM states along with opportunities for improvement.



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– **Jamie Scialdone**, director of regulatory operations

Focus on Health Authority Interactions

During the maturity assessment, Agios shared their vision to index, classify, and track all health authority interactions in Vault RIM, but their current processes didn't allow for that reality. They uploaded health authority communications to Vault and created a chronology log through a Vault report, but they didn't actively track commitments or health authority inquiries through the system. Instead, each product owner had a distinct process for capturing this data, whether in Vault, Microsoft Excel, or Microsoft SharePoint, and the team spent valuable time responding to internal and external requests with comprehensive and accurate information.

Success Highlights

To improve health authority interactions, Agios defined new requirements and identified what metadata they needed to capture in Vault Submissions. They implemented additional system features in May 2019 and now track more than 700 health authority questions in Vault. This will allow them to respond to inquiries in a consistent way and see trends across responses so they can avoid repeat questions and encourage faster decision making. Agios also tracks health authority commitments in Vault to ensure compliance and provide insight into upcoming and overdue commitments. They've transitioned away from using lists and Vault is now their system of record for all health authority interactions including commitments, health authority queries, and correspondence.

Jamie Scialdone, the director of regulatory operations at Agios, explained how the new functionality has helped her team operate more efficiently, "Now when we receive a health authority notification, our RIM manager creates a new record, it's quality checked, we start a workflow, and everything is captured in the audit trail. The process is much more streamlined and our regulatory team members have visibility into all queries across the portfolio."

In addition to new process flows, Agios replaced manual notifications with flash reports for each commitment owner. Currently, those reports cover Development Safety Update Reports (DSURs), Postmarketing Requirements (PMRs), Periodic Adverse Experience Reports (PADERs), and the Investigator's Brochure (IB) Annual Review. In the future, Agios plans to summarize key report metrics in a visual dashboard so they're more digestible, especially for new users. They will also share this data in departmental meetings and through internal newsletters for greater cross-functional visibility.

