Global Submission Planning at Bristol-Myers Squibb

BMS is transforming their operations with an authoritative source for regulatory information, including new processes for scheduling submissions and developing submission content plans.



The Global Regulatory Team

maintains a calendar of all

BMS submissions globally.



Country-specific planning records capture affiliates' input into the corporate planning process.

> **Proposed dates reviewed** by international strategy leads in headquarters.

other core information.

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Global Regulatory Team evaluates feasibility of affiliates' dates and establishes cross-functional alignment with clinical, CMC, manufacturing, regulatory operations and others on planned submission dates.

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Cross functional governance committee evaluates whether teams can deliver dossier by proposed date(s) before approving plan.

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Governance-approved dates are entered into **Global Submissions Plan** and notifications sent to all involved.



GRANULAR CONTENT PLANNING BEGINS 12 MONTHS AHEAD OF THE APPROVED COMPLETION DATE



Functional area



Country Tracking Records

Country-specific tracking records aggregate all submissions and correspondence related to the original business objective.



Approved dates don't change without governance sign-off.

Submission Content Plan

The RIM system auto-generates a submission content plan based on pre-defined parameters.

representatives commit to completion dates for each component.

Submission Documents

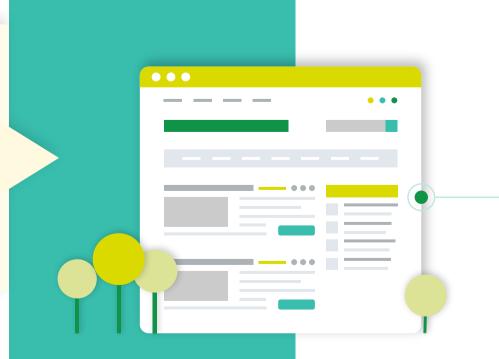
A dashboard shows completion status of each module as documents are authored, reviewed, and approved.

Personalized dashboards show planned dates for relevant submissions by month, country, or indication.



Archived Dossier

The final published output is archived within the global RIM platform and linked to the original submission planning record.





Tracking baseline, target, and approval dates for each component provides metrics for continuous process improvement.



Final content plan with approved documents, provides basis for local dossiers in each reference country.