Establishing a Content Management Process as a Late Stage Company

There are many key milestones on the pathway to the commercial launch of a pharmaceutical product. For the purposes of our analysis, we focused on the key milestones at the point in which the Phase 3 trial is approaching completion: Completion of Patient Enrollment for Phase 3 Trial, Top-Line Phase 3 Results, NDA/BLA Submission, and FDA Approval and Commercial Launch. Conducting an analysis of past and present clients, we have examined during which key milestones clients typically deploy a Content Management Process (CMP). Specifically, we analyzed those clients that have reached the milestone of Completion of Patient Enrollment for Phase 3 Clinical Trial which we have defined as being Late Stage clients.

Key Findings:

Deployment of a CMP is an important step in an organization's preparation for FDA Approval and Commercial Launch. An emerging trend in the industry is for companies to begin planning and deploying their CMPs earlier as this increases a company's chances for a more successful commercial launch and faster scalability.

The figure below illustrates the timing of our Late Stage clients' CMP deployment.

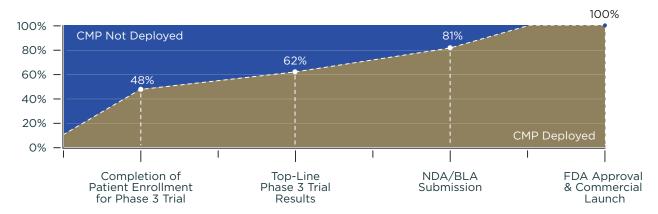


Figure 1: Content Management Process (CMP) Deployment Timeline

As can be seen from Figure 1 above, nearly half of Late Stage clients in our dataset had deployed their Content Management Process by the Completion of Patient Enrollment for Phase 3 Trial milestone. In addition to this, the percentile point increase of companies with a deployed CMP was greatest between pre-patient enrollment and the completion of patient enrollment for Phase 3 clinical trial (over 30 percentile points). This indicates that the majority of organizations are investing in the deployment of a CMP as the Phase 3 trial progresses. Earlier deployment of this process allows an organization more freedom to focus on process optimization and preparation as FDA approval is neared.