



Pharmaceutical Records and
Information Management Organization

A consortium of pharmaceutical companies committed to establishing effective, legally compliant, quality-driven records and information management programs through collaborative and innovative industry initiatives.

▶ PRIMO's mission is to develop and advance records and information management solutions in the pharmaceutical industry, provide an open forum for pharmaceutical records and information management professionals to discuss the unique information management challenges and opportunities in the industry and to share information and best practices, and promote recognition of the vital role of effective information management in the research-based pharmaceutical industry.

Core Goals

- > Discuss and develop solutions, strategies and tools relevant to managing pharmaceutical records and promoting effective information management.
- > Provide a forum for dialogue, benchmarking and consensus-building on issues of common concern.
- > Contribute to more effective regulations and standards by communicating PRIMO's consensus positions.
- > Develop materials that underscore the business case and help internally educate employees and top executives on the need for and increasing complexity of information management.

Priorities and Recent Deliverables

- > **Model Records Retention Schedule**
PRIMO has developed a comprehensive model records retention schedule tailored to the biopharmaceutical industry. PRIMO's Model Schedule includes retention timeframes, relevant regulatory citations, as well as business rationale for retention, and will be regularly updated and refined based upon emergent requirements. As such, it is a valuable tool for members.
- > **Legal Analyses and Other Compliance Tools**
Provide regular updates on relevant case law and regulations impacting pharmaceutical information governance and when needed develop legal memoranda and related tools to promote compliance. Recent examples include the permissibility of destruction of paper source documents and autoclassification of unstructured electronic content in pharmaceutical companies for records management purposes.
- > **Information Sharing and Benchmarking**
Progress sharing of key documents among PRIMO members (e.g., information management policies, email management policies) and consider benchmarking initiatives. Consider opportunities to leverage prior benchmarking on email management through, e.g., development of best practices for email management.

Membership

Value and Benefits of Membership

- > Information governance is a complex area; ensuring compliance with the myriad of global laws can be time-consuming, confusing and costly. PRIMO is a focused, flexible organization that moves quickly to agree on priorities and advance development of concrete deliverables. PRIMO members leverage off each other and share the fixed consortium costs, saving a range of costs they would have incurred individually.
- > Cross-fertilization of ideas can generate new insights or perspectives. PRIMO membership provides facilitated opportunities to learn best practices from other similarly situated companies and provides access to timely tools, education, and knowledge, including benchmarking data.
- > An industry's power to influence regulatory and standard-setting bodies is strongest when the industry articulates shared goals with a common voice. Collaboration through PRIMO allows companies to collectively develop best practices and common positions on records and information management and can broaden and enhance each member's network of RIM experts.
- > PRIMO Membership provides the opportunity to:
 - ◆ Interact with industry leaders.
 - ◆ Participate on collaborative and emerging working group efforts.
 - ◆ Take part in regular confidential surveys and benchmarking exercises.
 - ◆ Stay up-to-date on current regulatory requirements in the US, Canada, Europe, Australia, Asia.
 - ◆ Participate in PRIMO workshops and internal events such as expert roundtables.
 - ◆ Effectively influence external environment.

Membership Details:

- > Pharmaceutical and medical device companies with interest in records management and information governance are eligible for consortium membership.
- > Member companies are entitled to two seats on the Board of Directors and have unlimited representation on Working Groups and Roundtables.
- > Board of Directors defines budget and companies share pro rata in all fees and disbursements. The 2020 budget is capped at \$12,000 per company.

Please contact the PRIMO Secretariat for more information about membership.

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Current Members:

Abbott
AbbVie
Alexion
Amgen
Astellas
Baxter
Biogen
CSL Limited
Eli Lilly and Company
Merck & Co., Inc.
Novartis
Novo Nordisk
Pfizer
Regeneron
Roche/Genentech
Sage Therapeutics
Spark Therapeutics
Takeda