

A consortium of pharmaceutical and medical device 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 and medical device industries, provide an open forum for records and information management professionals to discuss unique challenges and opportunities, to share information and best practices, and promote recognition of the vital role of effective information management in the research-based pharmaceutical and medical device industries.

Core Goals

- > Discuss and develop solutions, strategies and tools relevant to managing pharmaceutical and medical device records and promoting effective information management.
- > Provide a forum for dialogue, benchmarking and consensus-building on issues of common concern.
- > Contribute to more effective programs and standards by documenting 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 and medical device industries. PRIMO's Model Schedule includes retention timeframes, relevant regulatory citations, and record type examples. The Model RRS is regularly updated and refined based upon emergent requirements, making it a valuable tool for members.
- > Other Guidance Documents and Compliance Tools
 Through collaboration, PRIMO has developed in depth guidance documents to assist
 information management professionals with lifecycle management in information systems,
 automated disposition, managing records with event-based triggers, clinical site investigator
 records, and deal support for mergers, acquisitions, divestitures, and closures.
- Information Sharing and Benchmarking The PRIMO Secretariat facilitates sharing of key documents among PRIMO members (e.g., information management policies, email management policies) and supports benchmarking initiatives. The PRIMO Planning Committee considers opportunities to leverage prior benchmarking to develop best practices or launch Working Groups.

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 participation in Working Groups and Roundtables.
- > Board of Directors defines budget and companies share pro rata in all fees and disbursements. The 2025 budget is capped at \$12,000 per company.

Please contact the PRIMO Secretariat for more information about membership.

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Current Members: **←**·····

AbbVie Amaen Astellas AstraZeneca Baxter BeiGene Biogen Cerevel CSL Limited/Segirus Eli Lilly **Emergent** Faraday Gilead GlaxoSmithKline Incyte Merck & Co. Novartis Novo Nordisk Pfizer Regeneron Roche/Genentech/Spark Takeda Teva

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