

Digital Signatures for CROs

CoSign for Clinical Research Organizations

The CoSign® digital signature solution delivers a truly collaborative technology for CROs, where both internal and external personnel can easily and securely create digitally signed electronic records that are FDA and EMEA compliant. CoSign allows for record validation and proof of signer identity, intent, and document integrity without the need for expensive, complex or proprietary technology. Digitally signed electronic records are portable, sustainable and trusted throughout a collaborative clinical ecosystem, including internal employees and external partners, suppliers, clients, and even regulators.

APPLIED CLINICAL TRIALS

“Strong signatures are critical to the success of any e-clinical solution... and thanks to new solutions, are no longer out of reach for smaller companies.”

CoSign is ¼ of the cost of managed PKI digital signature services and 1/10 of the cost of building a system in-house.



The most widely-deployed digital signature system in the Life Science and Healthcare industries:

- » Thousands of FDA and EMEA GxP regulated applications use CoSign today.
- » Electronic records signed by CoSign have supported over 1,000 FDA, HACCP, USDA, EMEA, HIPAA, and SOX audits.
- » FDA regulated clients include:
 - » 4 of the top 10 largest CROs and over 25 CROs in total
 - » Over 10,000 CRAs
 - » Over 10,000 investigator sites and IRBs
 - » 5 of the top 10 Pharmaceutical companies and 3 of the top 10 Medical Device companies
 - » 50+ contract central labs
 - » Many of the leading service, SaaS, and clinical software suppliers including many of the leading CTMS (clinical investigator portals and trial master file) providers.

Common Applications for CROs

- » **Quality and Compliance documents** used to support FDA, EMEA and vendor audits, including seamless integration with Electronic Document Management and workflows systems, like Microsoft® SharePoint® and many others.
- » **Site Monitoring Trip reports**, by Clinical Research Associates (CRAs) and project managers, thereby meeting tight deadlines for submission to sponsors while saving thousands of dollars annually by eliminating paper-based costs. Some CROs have saved over ½ million dollars annually in priority mailing costs alone.
- » **Web-based Investigator Portals**, enabling external collaborators such as investigators and IRBs, labs and sponsors to sign regulatory packet documents, thereby expediting site and study initiation at lower costs and facilitating regulatory submissions.

Value Proposition - CoSign Digital Signatures

CROs experience a 3-6 month payback period with CoSign through:

Decreased Costs. Including people’s time as well as the hard costs of paper processes: paper, printing, copying, signing, scanning, routing, faxing, mailing, microfilming, indexing, storing, shredding, etc.

Increased Efficiencies. CoSign accelerates the pace of approvals particularly for documents requiring multiple signatures across multiple geographies and/or across multiple organizations.

Regulatory Compliance. In SOX, HIPAA, EMEA and FDA regulatory, quality and compliance applications, CoSign enables audits to be conducted electronically - quicker, more securely, and at a lower cost. Regulatory authorities also recognize digital signatures for e-submissions.

Increased Collaboration. CoSign bridges geographic, technical, and corporate boundaries, enabling electronic submissions and secure document exchange with outside parties such as government agencies, clients, suppliers, partners, etc. throughout an extended value chain or ecosystem.

Digital Signatures That Keep Your Business Moving

