

Cyber / Technical Security

- Secures mobile computing and cloud technology
- Enables secure and private remote access
- Prevents unauthorized access
- Protects confidentiality (prevents disclosure of protected healthcare information)
- Protects information integrity
- Protects availability of services, information, and business process systems



eHealth/Healthcare Regulatory Compliance

- Facilitates clinical trial processes
- Maintains integrity of information in Electronic Health Records
- Meets all requirements for signing EMA eSubmissions
- Meets all requirements for signing ePrescriptions for controlled substances



Workflow Automation

- Improves efficiency of any workflow involving signed forms



Collaboration and the Healthcare Ecosystem

- Enables collaboration with clinical sites, in research environments, and with JVs and partnerships



Au **AUTHENTICATION**—The process that proves the user's identity to the computer system. The SAFE-BioPharma standard assures use of strong authentication by requiring two-factor authentication which proves, *with greater certainty, an individual's cyber identity. These factors may be something the user has (e.g. a cell phone to which a one time password may be sent), something the user knows (e.g. a username), or something the user is (e.g. fingerprint, iris scan, or other biometric).*

Ip **IDENTITY PROOFING**—The process of proving an individual's legal identity through the presentation and review of documentation and/or biometric evidence. Before a SAFE-BioPharma identity credential can be issued, the individual must undergo a process providing verifiable evidence of identity. The process is aligned with national and international laws, regulations and standards.

Ds **DIGITAL SIGNATURE**—The signature specified in the SAFE-BioPharma standard provides the strongest proof of the identity of the person who applied it. These digital signatures are based on cryptography, are legally-binding, and cannot be denied by the signatory. Digital signatures compliant with the SAFE-BioPharma standard are the single strongest form of electronic signature in existence.

li **INFORMATION INTEGRITY**—The cryptographic technology that demonstrates manipulation of a document after the document has been signed. Once a document has had a signature applied, it is protected from future change by revealing that change has occurred. While the specific change is not identified, the fact that the document has changed cannot be legally denied.