



## More time with *patients*, less time with *paper*

### Simplify clinical trial information exchange with Secure Access For Everyone (SAFE)

Multiple security devices and passwords are complex and inefficient. Typically, clinical investigators have relationships with many biopharmaceutical companies, regulators and labs. Each relationship requires investigators and their staff to use a different security device and password to access information systems. Keeping track of multiple devices and their passwords is confusing; it's inefficient, and it doesn't do anything to reduce or eliminate the real PAIN - mountains of paperwork.

SAFE technology changes that.

SAFE compliant technology is simple, secure and efficient. The SAFE Standard was developed and is managed by SAFE-BioPharma Association, a not-for-profit organization consisting of industry-leading biopharmaceutical companies. SAFE members, when working with others in the SAFE community (e.g., agencies, clinical investigators, etc.), can use a single, easy-to-use electronic identity key for all their business and regulatory transactions.

The SAFE identity credential provides legally enforceable and regulatory compliant electronic signatures

for exchanging data with SAFE companies and regulators. They can be used to sign a variety of electronic medical records and clinical trials documents, including FDA Form 1572 CV, IRB approvals, financial disclosures, site study documents, drug sample releases, protocol acceptance documents, case report forms, contracts and many others.

SAFE electronic signatures are legal and comply with government regulations globally, enabling the virtual elimination of paper copies and files. Less paper makes managing clinical trials less confusing and your clinic operates more efficiently. That means you can spend more time doing important things—like working with your patients.

#### SAFE provides clinical investigators with:

- Globally accepted, legally enforceable, regulatory compliant credentials (“keys”) for electronically signing documents
- Standardized policies and procedures
- An effortless end user experience for signing documents and controlling access to data
- Implementation guidelines and procedures for regulatory compliance
- Simple and fast turnaround time for submissions

*“SAFE supports our clinical research by simplifying submissions and accelerating turnaround times for regulatory communications. SAFE also provides a comfort level for doctors in the use of clinical applications like e-prescribing and the electronic medical record.”*

*Dr. Randall Huling  
Olive Branch Family Medical Center  
Olive Branch, MS*



## Who is SAFE-BioPharma Association?

SAFE-BioPharma Association is a not-for-profit organization sponsored by the Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries Associations (EFPIA). SAFE-BioPharma is funded and led by leading biopharmaceutical companies with input and collaboration from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

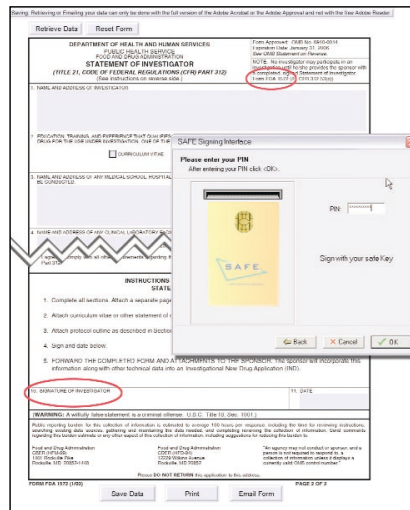
The mission of SAFE-BioPharma is to deliver unique electronic identity keys for legally enforceable and regulatory compliant electronic signatures across the global biopharmaceutical environment.

SAFE-BioPharma member companies include Abbott Labs, Amgen, AstraZeneca, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson, Merck, Pfizer Inc., Procter & Gamble, Sanofi-Aventis, INC Research and Tap Pharmaceuticals.

## Free membership and identity credentials for clinical investigators

Enjoy the benefits of a more efficient clinical trial process created by SAFE technology. Clinical investigators can join SAFE as Associate Members — it's free. You and your staff will receive SAFE identity credentials to sign and protect your electronic documents when working with SAFE member companies.

For more information, please visit [www.SAFE-BioPharma.org](http://www.SAFE-BioPharma.org).



SAFE-BioPharma Association  
Secure Access For Everyone