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Signatures and Authentication for Everyone

Accelerating Drug Development Via Interoperable Digital Identities, Signatures and Cloud Computing

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ISE

The Environment

- **Everything about the biopharmaceutical business model changing dramatically**
  - Pharma deals with many, many external partners
  - Urgent need to reduce R&D cycle times and costs
- **Regulatory agencies moving to fully electronic**
- **Health information technology**
  - USG payments and mandates: ePrescribing (DEA), eHealth Records
  - New HIPAA requirements and penalties re Personal Health Information
- **Security and privacy issues in moving to the cloud**

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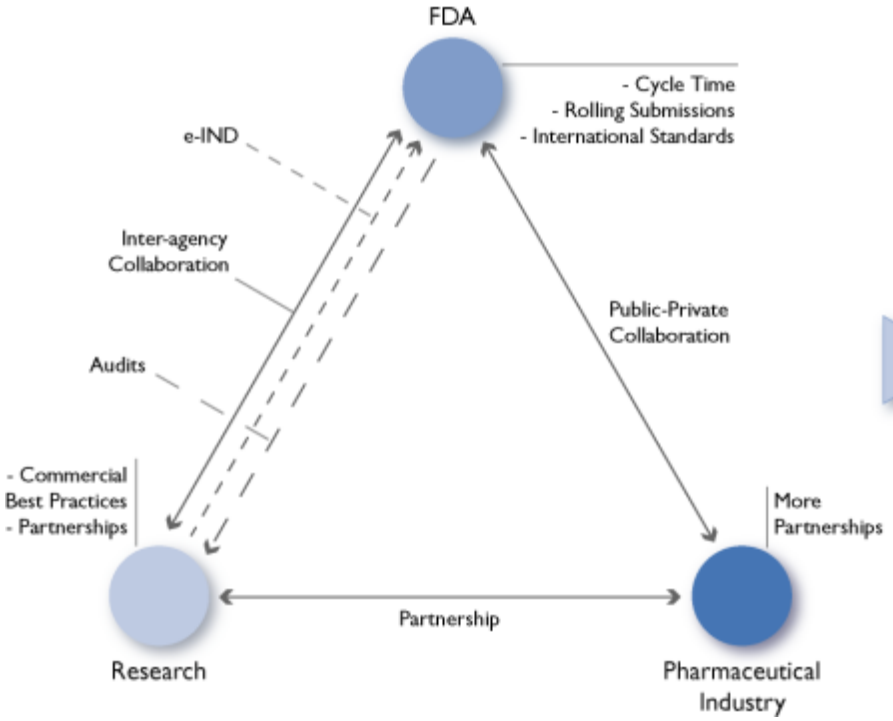
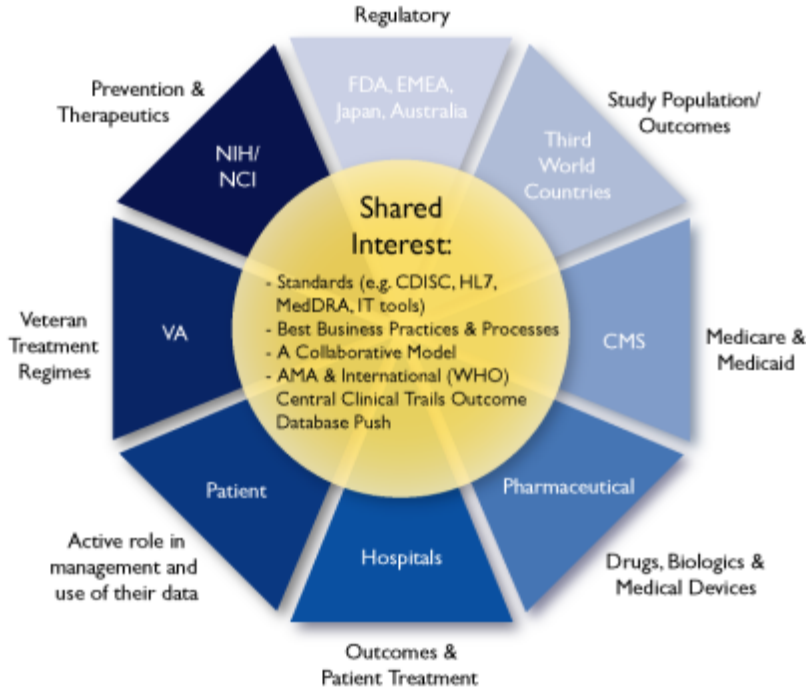
The R&D Landscape is Changing

The emerging new model is 'community focused' as government, academia, industry and patients collaborate to find a cure.





Source: Booz Allen Hamilton, 2009

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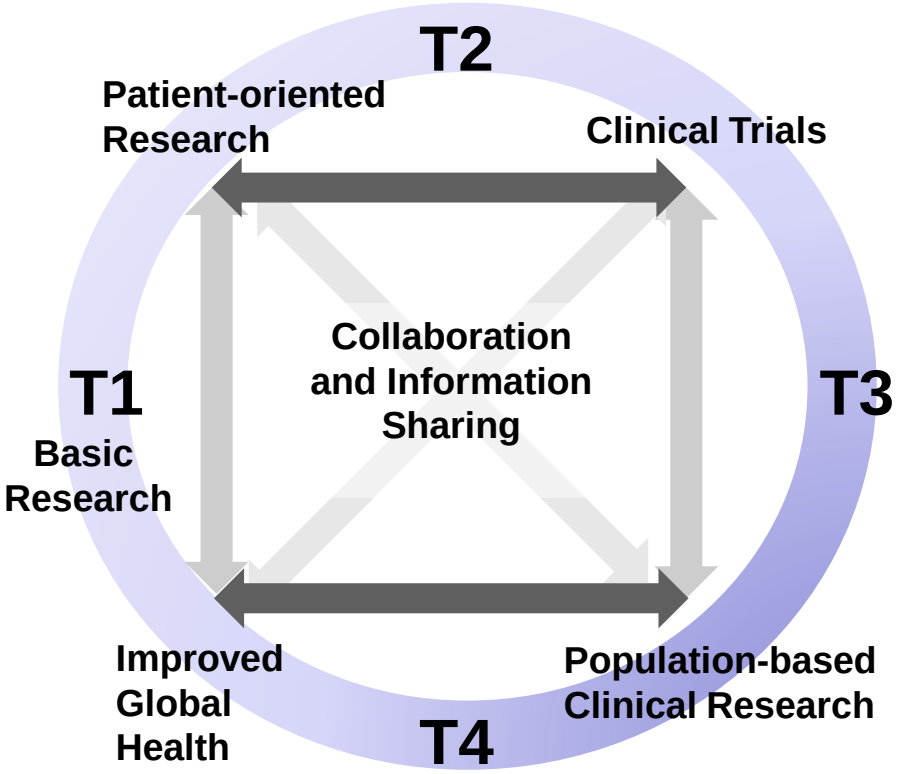
The Way We Do Business is Changing

We need to work with a greater and more diverse set of players. We also need lots of coordination at each juncture through discovery, development and delivery, from bench to bedside and back.



Source: Dubman, et. al., "Enabling Translational Medicine with Informatics", 2011

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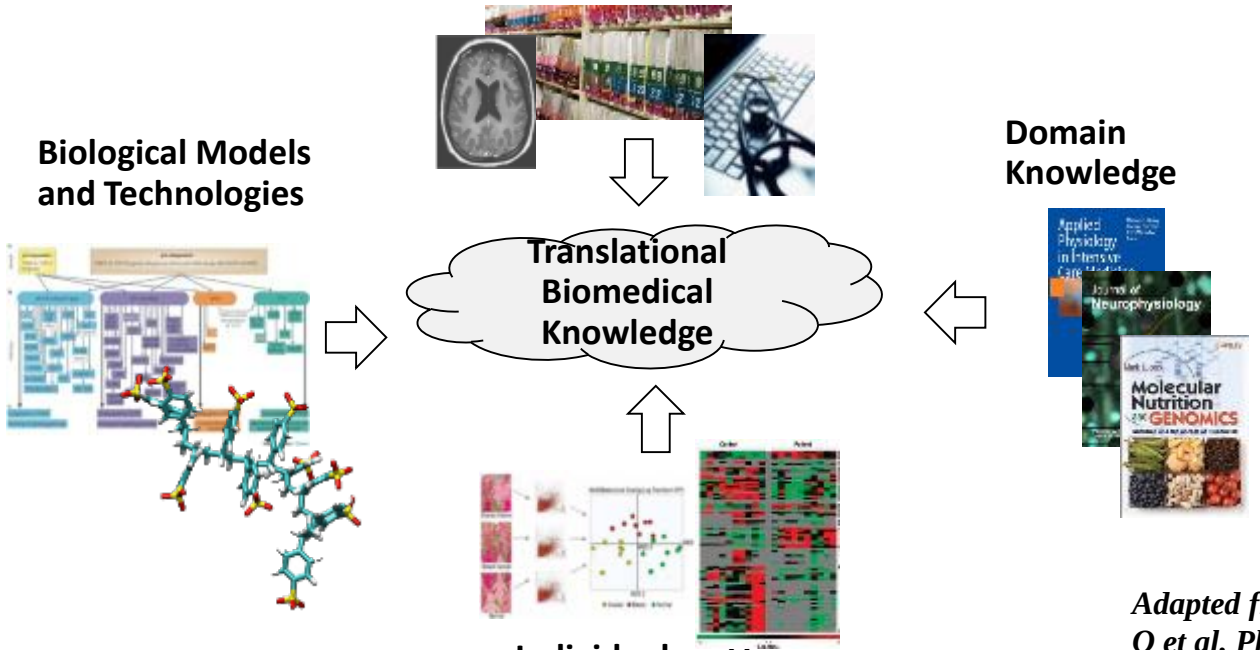
Data Management Needs are Changing

We need the ability to share a diverse and growing volume of information easily and securely.



Adapted from Payne P R O et al. Physiol. Genomics 2009;39:131-140

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Current Identity Management Approach

- **Gartner:**
  - Industrial age approach – borders stop at enterprise
  - On-line identities – user name/password issuance and resets --- very costly, redundant
  - Doesn't map to how companies interact in real world
  - Risks honeypots of Personally Identifiable Information
- **Proprietary solutions**
- **May or may not have identity proofing**
- **May or may not link identities to signatures**
- **Tower of Babel**

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Why an Interoperable Digital Identity Standard?

- **Simplify identity management**
- **Standardize trust**
- **Speed provisioning of identities**
- **improve security**
- **Safeguard privacy**
- **Provide risk mitigation**
- **Legal enforceability**
- **Regulatory compliance – USFDA, European Meds Agency**
- **Single identity that can be used across all life science/healthcare community**

The SAFE-BioPharma Standard

- **SAFE-BioPharma is a trust authority focused on the life sciences and healthcare sectors (established 2005)**
- **SAFE-BioPharma maintains two trust standards and certifies identity providers to those standards (PKI and non-PKI)**
- **PKI – Federal Bridge CA compliant**
  - Strong identity trust through standardized identity proofing process (LOA3)
  - High-level assurance binding identity to a digital signature
  - Utilizing NIST and Federal government technical standards
  - Contract-based governance, legal and risk mitigation framework
  - Mapped to laws at US state and Federal levels, EU and MS levels
  - Interoperable identity across all USG and linked cyber-communities
  - Meets Food & Drug Administration, European Medicines Agency, and Drug Enforcement Administration requirements

The SAFE-BioPharma Standard

- **Non-PKI – SAFE-BioPharma is a Federal Identity Credentialing and Access Management (FICAM) Trust Framework Provider**
  - SAFE-BioPharma certifies Identity Providers at NIST LOAs 2 and 3
  - Provides identity trust through standardized identity proofing process
  - Utilizing NIST and Federal government standards
  - Contract-based governance, legal and risk mitigation framework
  - Mapped to laws at US state and Federal levels, EU and MS levels
  - Interoperable identity across all USG and linked cyber-communities
  - LOA3 meets DEA requirements for Electronic Prescribing of Controlled Substances

4BF – Issuers and Trust Relationships

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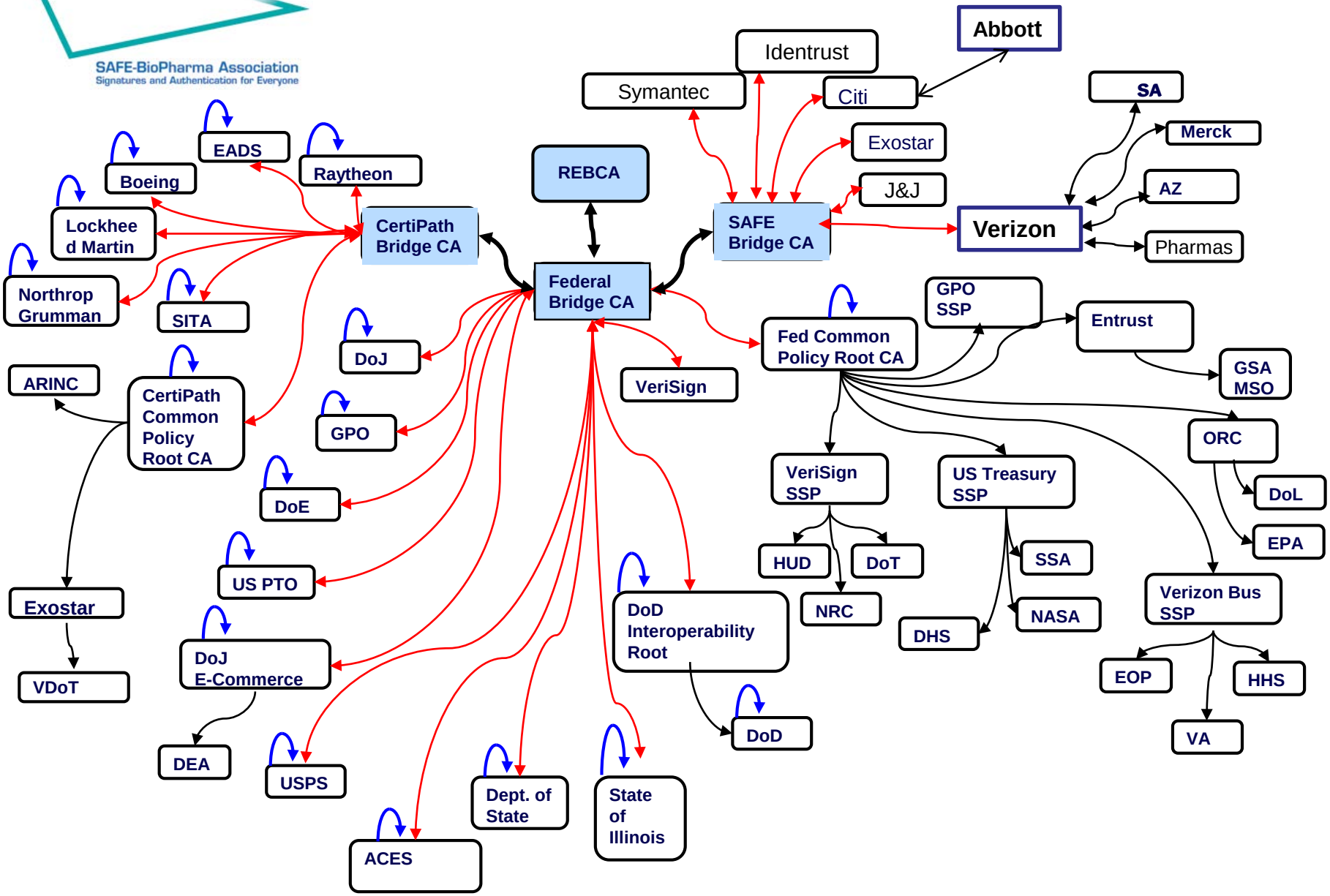

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National Cancer Institute Business Case

- FDA moving to electronic submissions
- Operational Efficiency Working Group (OEWG)
- Budget constraints
- Complexity of interactions among many partners
- Go-green initiatives
- IT security measures

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Why Clinical Trials Evaluation

- The mission of the Cancer Therapy Evaluation Program (CTEP) is to improve the lives of cancer patients by finding better ways to treat, control and cure cancer.

- CTEP sponsors clinical trials to test promising new investigational agents. One mechanism is through the cooperative groups which lead randomized phase 2 and phase 3 trials.

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CTEP by the Numbers

- Currently sponsors over **100** Investigational New Drug Applications (INDs) with the FDA
- Over **700** active clinical trial protocols testing new investigational agents
- Activate **130** new protocols/year
- Approx. **33,000** patients accrued/year to NCI supported trials
- Over **80** clinical collaborative agreements with pharmaceutical partners
- An average of **80** MTAs executed per year

Protocol Process

- Group submits a concept/ LOI for CTEP review and approval
- Signed acknowledgement letter goes back to the Group upon receipt
- Signed letter goes back to Group after CTEP review (consensus review of changes)
- Signed drug approval letter must be submitted by collaborating pharmaceutical partner
- Protocol submitted and reviewed; signed comment letter goes back to site
- Revised protocol resubmitted
- CTEP approval via signed letter
- Amendments follow last few steps also

CTEP's Agreement Coordination Group (ACG) - Phase II of Pilot

- CTEP/DCTD as IND holder negotiates with pharmaceutical collaborators
- Results in various documents – MTA, CRADA, CTA, CDA, Correspondence and Forms
- Expansion of pilot to cover generation of these documents
- Critical to speeding up process
- Meets OEWG recommendations
- Strives to help meet drive towards automation
- Goes beyond CTEP-ESYS documents
- **Leverages interoperable digital identities/signatures – Federal Government and SAFE-BioPharma**

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A Comparison of Electronic and Digital Signature Features

Feature	Electronic Signatures	Digital Signatures
Tight binding to the individual through face to face or other strong identity verification	No	Yes
Legally enforceable	Maybe	Yes
Supports strong non-repudiation	No	Yes
Maintains persistence, can be verified after certificate expires	N/A	Yes
Legal equivalent of hand written signature	Yes	Yes
Scalable	Yes	Yes
Tight binding to document signed (prevent “forgery”)	No	Yes
Detect document tampering	No	Yes

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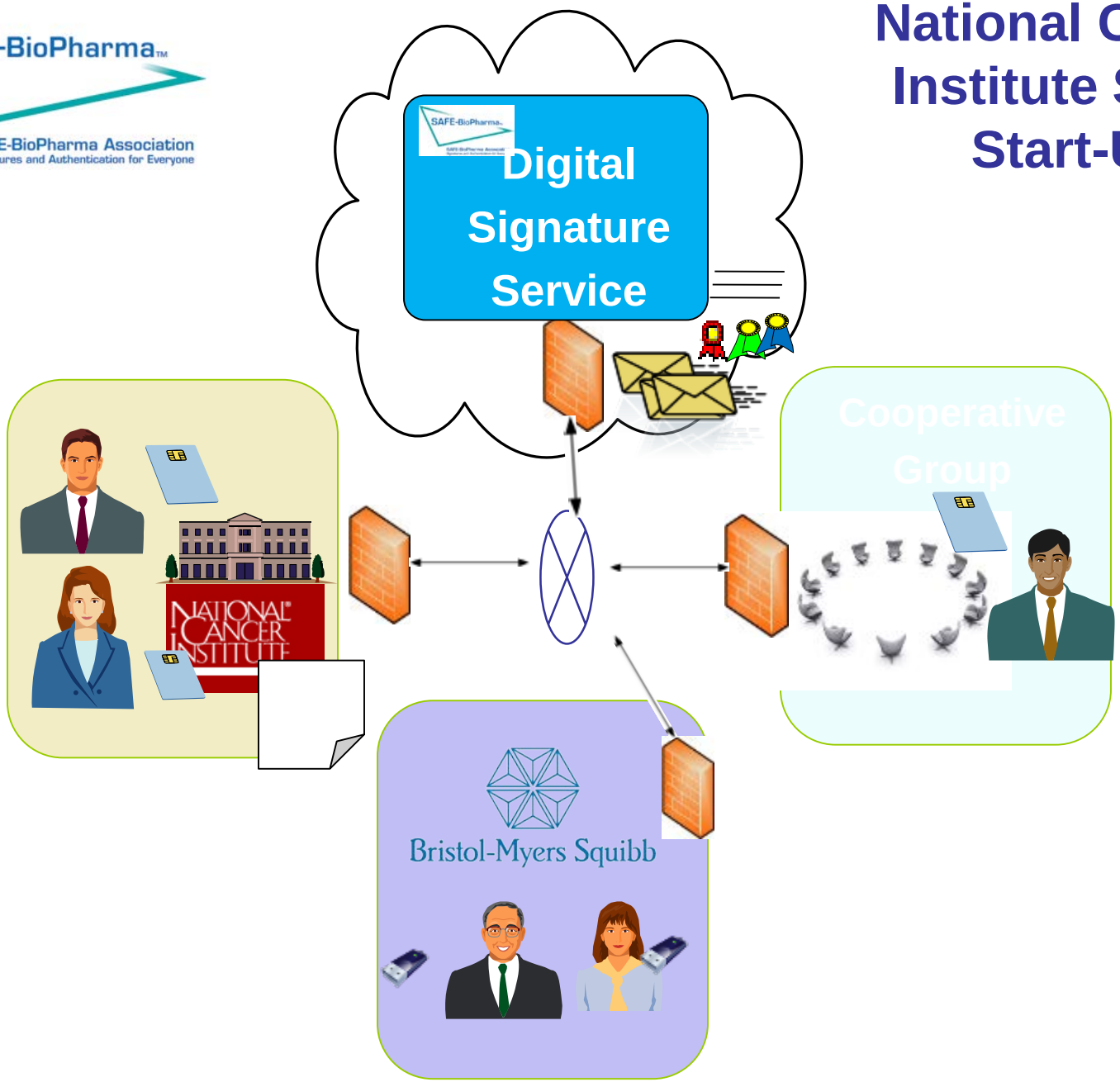
National Cancer Institute Study Start-Up



CTEP's Agreement Coordination

- Successful use of NIH/NCI PKI credentials and PIV card readers to login and sign agreements
- Successful integration of digital signing service into existing ACG workflows
- Successful use of digital signing service document management and tracking options
- Monitored, reported, and resolved user and digital signing service system errors
- 143 Official Correspondences signed and 100 MTAs and 14 CDAs partially-executed through digital hosting service
- Digital signing service utilized by ACG, on average, 3-4 times per week
- Use of digital signing service represents a time savings of 1 business day per Official Correspondence and 3-5 business days per MTA
- Use of digital signing service represents a cost savings of $800 per year for MTAs (avg. 7 MTAs per month)
- Time savings of 2.2 hours for each wet signature replaced by digital signature

CTEP's Agreement Coordination

- ACG future plans for Phase II of Pilot
  - Expand digital signing service use to other document and agreement types
  - Upward expansion of digital signing usage to the division and institute level
  - Inclusion of CTEP pharmaceutical collaborators into the digital signing service pilot
  - Continue to monitor digital signing service errors, usage, time and cost savings, and system integrity and reliability

Examples of Use of SAFE-BioPharma Standard

Use Case	Company
ELNs – basic research	Abbott (including China), BMS, GSK, Pfizer, Sanofi, Aventis Pasteur (vaccines)
Contracts, SOWs	J&J, GSK, Premier, Oxford, MWB Consulting, IPS, Allergy & Asthma Inst.
Physician Signatures, eSampling	SNAP Diagnostics, AZ, Novartis
ePrescribing (authentication and dig sig)	Allscripts, Omnicare
Purchasing	Premier
Clinical Research	Sanofi-Aventis, BMS, National Cancer Inst., Forest
Research Collaboration	BMS, National Cancer Institute, Sanofi-Aventis
Alliance Management	BMS, GSK
Regulatory Submissions	AZ, BMS, GSK, SA, Eli Lilly, Forest, J&J, Alkermes
Document management system	McDougall Scientific
Legal signatures	Veroha
Paperless business/regulatory environment	Amarin, MWB Consulting, SAFE-BioPharma

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Game Changers

- **Intense pressure on firms to reduce costs, speed research.**
- **Collaboration, collaboration, collaboration**
  - Movement to cloud to improve efficiencies and reduce costs
- **Improved identity proofing processes; flexible, mobile use; rapidly declining costs**
- **Federal government payments to doctors and hospitals for HIT; criminal penalties for HIPAA violations; 2014 interoperability requirements**
- **Governments and standards bodies focused on trust**
- **400,000 prescribers receiving SAFE-BioPharma credentials which can be leveraged by entire SAFE community**
- **Disruptive business model for identity providers. Not identity provisioning that is the core business but leveraging those identities with value added services**

SAFE-BioPharma Digital Signatures:
Enjoy the Benefits

- **Legal Enforceability:** SAFE-BioPharma signatures meet 3 key legal criteria.
  - **authentication**, you are sure of the identity of the person who provided the signature.
  - **integrity**, you are sure the document has not been altered since it was signed.
  - **non-repudiation**, you are sure that the sender cannot deny signing the document.
- **Regulatory compliance.**
  - The SAFE-BioPharma standard meets or exceeds regulatory guidelines for 21 CFR Part 11 and HIPAA;
  - the standard meets similar international guidelines, including the Directive 1999/93/EC of the European Parliament and of the Council, and ensures that new versions comply with emerging regulations
- **Strong Security**. The standard ensures security and data integrity. With two-factor authentication, the standard uses public key infrastructure (PKI) to apply digital signatures to documents and to assure the integrity of their content.
- **Global.** SAFE members are global companies and require a global standard, both for internal and external use.

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- ✓ *Please visit the SAFE-BioPharma website*: http://safe-biopharma.org/
- ✓ *Please visit the 4BF website:* http://www.the4bf.com/
- ✓ *Watch the SAFE-BioPharma introductory video: http://www.safe-biopharma.org/video.htm*