Interagency Advisory Board

Meeting Agenda, September 27, 2010

1. **Opening Remarks**
2. **Transportation Worker Identity Credential Program Status Update** *(John Schwartz, TWIC PM)*
3. **Virginia First Responder Authentication Credential Status Update** *(Mike McAllister, Virginia Department of Transportation)*
4. **Sanofi-Aventis Implementation of Digital Identity Using SAFE-BioPharma** *(Peter Loupos, VP Prospective and Strategic Initiatives)*
5. **Identity Business Architecture 2.0—Beyond PIV** *(Corinne Irwin, NASA)*
6. **Update on Government Smart Card Training** *(Randy Vanderhoof, Executive Director of the Smart Card Alliance)*
7. **The Difference Between PIV-I and PIV-C** *(Tim Baldridge, NASA)*
8. **Closing Remarks**

Enabling Fully Electronic Global Business Processes Through Digital Signatures

Peter Loupos
Vice President, Prospective & Strategic Initiatives
Sanofi-Aventis

sanofi aventis
Because health matters

Topics

- Why do we need a standard for interoperable digital identities and signatures?
- How the standard is being used
- How sanofi-aventis is using the standard
- Helping to improve human health:
  - The National Cancer Institute pilot
- The future vision

The imperative to move into the digital age for BioPharma and Its Partners

- Extreme changes underway in medical research and in the structure of the research industry
- Cost and complexity has created a crisis in R&D productivity
- Need for rapid, interactive collaboration between pharma, healthcare providers, research institutions, and other stakeholders globally
- Necessary advances in Regulatory Science require fully electronic submissions, review, analysis, and response
- Healthcare mandate for EMRs in United States and Europe coupled with advances in translational medicine
- Constantly changing business models

Industry Collaboration to support innovation and productivity: The SAFE-BioPharma Digital Identity & Signature Standard

- **Initiative Started in 2005 by Biopharmaceutical Industry to:**
  - Create a trusted identity authentication and non-reputable Digital Signature Standard across industries and geographies
  - Meet rigorous and unique legal and regulatory requirements in the complex, multi-stakeholder biopharmaceutical and healthcare sectors
  - Enable risk mitigation through technology and vendor neutrality
  - Transform the biopharma and healthcare communities to fully electronic
- **Member-governed, Non-profit Collaborative Industry Organization**

Amarin	IPS Research	PDS Biotech
Amgen	Johnson & Johnson*	Pfizer*
Abbott	McDougall Scientific	Premier Purchasing
AstraZeneca*	Merck*	Roche
Bristol Myers Squibb*	MWB Consulting	Sanofi-aventis*
Eli Lilly	National Notary Assn.	SNAP Diagnostics
GlaxoSmithKline*	Oxford Outcomes	St. Renatus

* Board Member

Examples of How the SAFE-BioPharma Standard Is Being Used Today

Use Case	Company
Electronic Lab Notebooks – basic research	Abbott (including China), BMS, GSK, Pfizer, SA/Aventis Pasteur (vaccines)
Contracts, SOWs	J&J, Pfizer, GSK, Premier, Oxford, MWB Consulting, IPS Research, PDS Biotech
Physician Signatures	SNAP Diagnostics
Purchasing	Premier
Clinical Research	Sanofi-Aventis
Alliance management	BMS
External Partner Authentication	BMS, GSK
Regulatory Submissions	AZ, BMS, GSK, SA, Eli Lilly
Document management system	McDougall Scientific
Collaborative research	BMS with NCI and Research Institutions
Paperless business/regulatory environment	Amarin, MWB Consulting

Motivation to evolve to electronic processes in Biopharma

- R&D productivity is impacted by inefficient processes:
  - Stifles innovation
  - Slows the availability of promising new treatments
- The current paper based model is expensive and not sustainable:
  - 40% of all R&D costs are linked to paper-based processes (NEJM)
  - $30 cost (minimum) per “wet” signature (SAFE member company)
  - Scanning/printing costs estimated at $.74per page
- Costs associated with shipping, archiving, and accessing hardcopy records
- Paperless processes are more secure and accessible
- Can be audited easily and inexpensively
- Saves time, experience from SAFE Biopharma members:
  - Preparation of submission forms reduced from hours to minutes
  - Records management / archiving reduced
  - Using electronic workflows to review, approve, sign documents, approvals that took days take minutes
  - Responsible and green

Electronic versus digital identity

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	No	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

SAFE in Electronic Lab Notebooks

- SAFE signatures offer significant benefits and improvement in the management of electronic laboratory notebooks
- Patent requirements are fully satisfied by the SAFE-BioPharma solution:
  - Authorship of the information is clearly ascertainable and ascribable to a specific party
  - Witnessing of the information is clearly ascertainable and ascribable to a specific party having no inventive contribution in the information
  - Authorship and witnessing entries are collected in a timely and unalterable form
- Electronic sources provide for easily searchable databases, analysis, and workflow
- SAFE signatures in ELN's significantly reduce discovery cost in Patent litigation especially in regards to liability for long term retention

SAFE in Clinical and Regulatory Affairs

- **Clinical Operations**
  - Clinical portal, SAFE signatures for Study Coordinators, Investigators, External Partners
  - First business case with 3 document types: estimated savings of >600 workdays saved over wet signatures
- **Regulatory Affairs**
  - SAFE signatures were launched in early 2010
  - Currently used for 1571 and 356h forms for all electronic submissions sent through the electronic gateway to the FDA
  - Progressive expansion planned through full integration within the submission publishing framework
  - Successful pilots executed with European Authorities

The SAFE-BioPharma Standard and Regulators

- EMA and FDA have announced publicly that fully electronic submissions will be required within the next few years
- FDA helped write SAFE-BioPharma standard:
  - CIO, PDUFA IT Team, 21CFR11 Council, CDER, CBER
  - FDA has received 10,000s of SAFE signed submissions since 9/06
  - The standard is interoperable with Federal government PIV cards used by government agencies and their contractors
- EMA helped write standard:
  - Five companies submitted eCTDs to EMA in a 2009 pilot
  - The standard meets the requirements for EU qualified signatures
  - SAFE digital identities meet EU data privacy requirements
- SAFE-BioPharma in Japan:
  - JPMA has established a Task Force on SAFE-BioPharma digital signatures
  - Hitachi to support implementations in Japan
  - Pilot with hospitals and pharma companies for pharmacovigilance eSubmissions

Other areas under investigation

- Legal
- Purchasing
- Pharmacovigilance
- Alliance Management
- Manufacturing

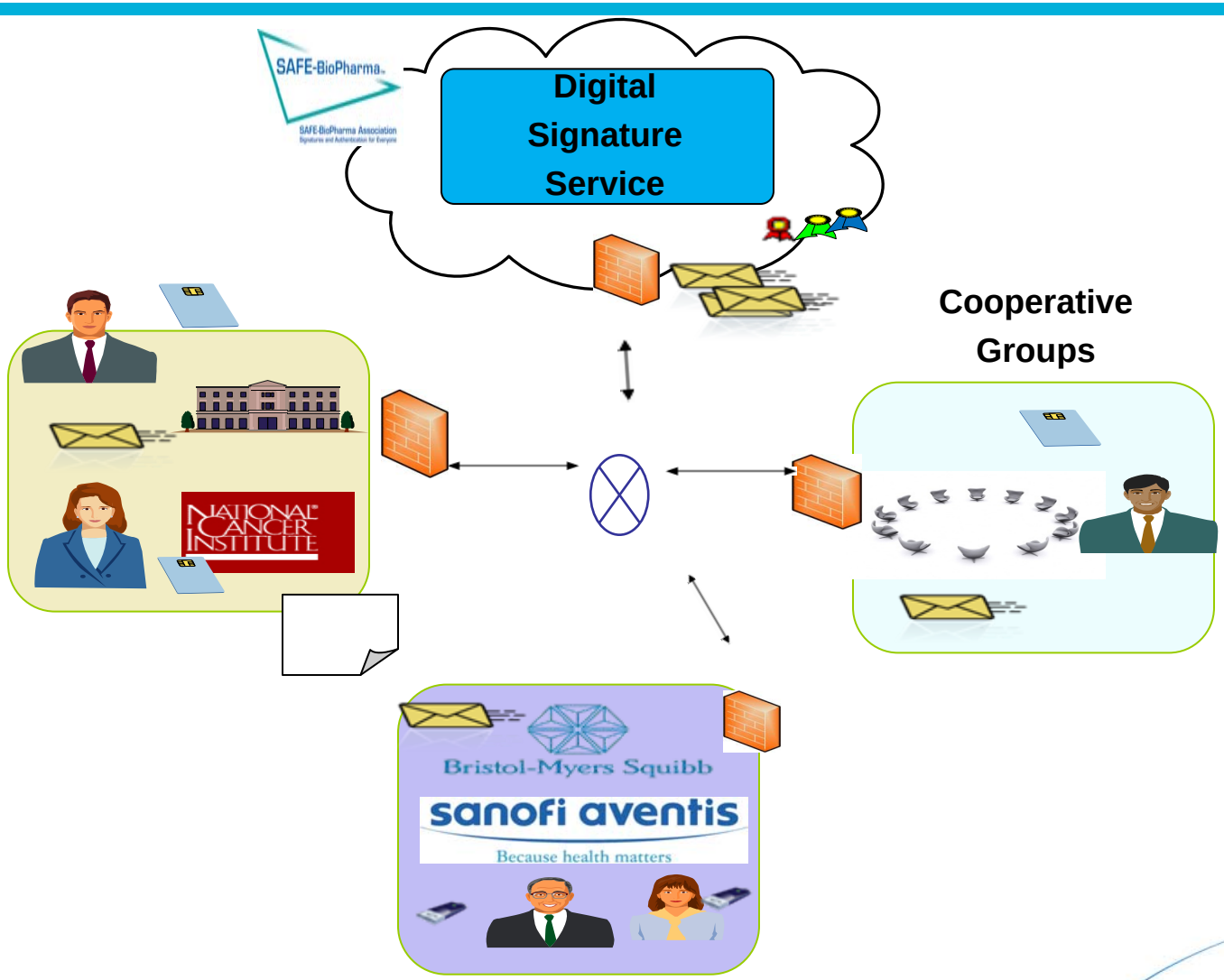
National Cancer Institute Digital Workflow Pilot

- **Forces impacting the NCI:**
  - FDA moving to electronic submissions
  - Operational Efficiency Working Group- mandate to reduce timelines for activation of new clinical trials
  - Budget constraints-save time; save money
  - Complexity of interactions and document management- streamline process
  - Go-green initiatives for NCI
  - Ongoing and enhanced IT security measures
- **Participants:**
  - Bristol-Myers Squibb
  - sanofi aventis

Pilot Focus – The Cancer Therapy Evaluation Program

- 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 phase II and phase III trials
- The largest sponsor of clinical trials in the world resulting in significant document volume - ideal for the pilot
  - Currently sponsors over 100 Investigational New Drug Applications with the FDA
  - Over 700 active clinical trial protocols testing new investigational agents
  - Approx. 33,000 patients accrued/year to NCI supported trials
  - Over 80 clinical collaborative agreements with pharma

Pilot workflow concept



Vision of the Digital Future

- **Information liquidity….**
- **Securely exchanged among trusted parties….**
- **Using a single interoperable digital identity for authentication and digital signing….**
- **Recognized by all stakeholders – regulators, healthcare providers, researchers, pharma, insurers, etc….**
- **For end-to-end electronic processes**

…. To help find and deliver promising new treatments for unmet patient needs and improve the quality of healthcare for all

Thank You

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