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**Creating an Electronic Platform for
Enhanced Information Management**

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DEFINING THE FUTURE

FDA Public Hearing, Dec 18, 2006

Docket No. 2006N-0464

This presentation discusses projects made possible by contracts from the Office of the National Coordinator for Health Information Technology (ONC), DHHS; and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) for the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The content is solely the responsibility of the author and does not necessarily represent the official view of ONC, IFPMA, or ICH.

HEALTH



Questions We Are Addressing – IV B, Third Party Entities

- What are your general viewpoints on a third party entity or entities providing services related to such an electronic platform?
- What are your views on the establishment of a public-private partnership to initiate formation of an electronic platform?
- How do you envision the business process modeling and nature of the third party entity or entities?
- What are the necessary attributes and characteristics of the third party entity or entities?
- What services could the third party entity or entities provide?
- What collaborative efforts by FDA with a third party entity would be beneficial to establish services?

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Interest/Qualifications in Electronic Information Exchange

- 
AHLTA for Department of Defense
- 
Federal Health Information Exchange / Bidirectional Health Information Exchange (FHIE / BHIE) for VA Hospitals
- 
Public Health Information Network (PHIN) for CDC
- 
Nationwide Health Information Network (NHIN) for HHS
- 
Medical Dictionary for Regulatory Activities (MedDRA) for IFPMA

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AHLTA – While devised as an acronym, it is properly used as the name of the DoD’s global enterprise EHR.

DoD – Department of Defense.

FHIE / BHIE – Federal Health Information Exchange / Bidirectional Health Information Exchange, linking VA hospitals and clinics, and most recently selected DoD facilities.

PHIN – Public Health Information Network, a set of standards and components for the coordination of public health across the nation.

NHIN – Nationwide Health Information Network, an ongoing program for the Office of the National Coordinator for Health IT.

MedDRA – Medical Dictionary for Regulatory Activities, the international standard for adverse events coding owned by the ICH.

MSSO – Maintenance & Support Services Organization, a “service” for maintaining the MedDRA standard terminology and ontology.

ICH – International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use, an international project that brings together the regulatory authorities of Europe, Japan and the United States and experts from the pharmaceutical industry in the three regions to discuss scientific and technical aspects of medical product registration.

IFPMA – International Federation of Pharmaceutical Manufacturers and Associations, non-profit, non-governmental organization representing research-based pharmaceutical industry associations from developing and non-developing countries.



Question: What are your general viewpoints on a third party entity or entities providing services related to such an electronic platform?

Multiple stakeholders

- Public & private entity participation to effectively represent all points of view

Different stakeholder needs

- Governance/implementation structure should promote flexibility & interoperability

Multi-national Stakeholders

- Governance/implementation structure should allow expansion beyond U.S. region

Workable models exist for Public-Private partnership

- ICH / IFPMA / MedDRA MSSO
- DHHS / ONC / NHIN

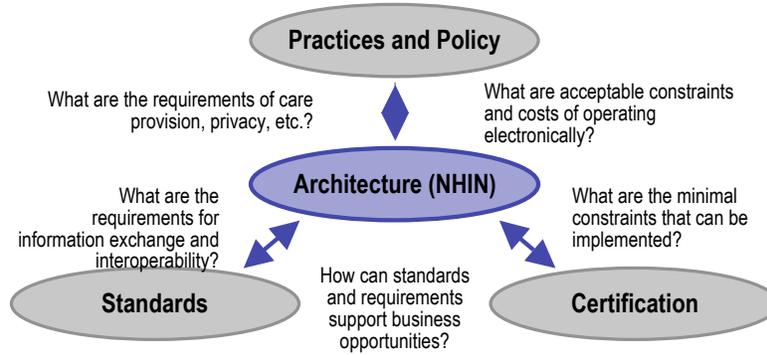
DHHS – U.S. Department of Health and Human Services

ONC – Office of the National Coordinator for Health Information Technology



Question: What are your views on the establishment of a public-private partnership to initiate formation of an electronic platform?

Collaborative developmental activities essential (NHIN Model)



From Office of the National Coordinator presentation to the American Health Information Community, 17 Jan 2006.

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Question: How do you envision the business process modeling and nature of the third party entity or entities?

Collaborative operational activities also essential (ICH/MedDRA Model)

- **Industry Association**
 - Contractual mechanism, infrastructure, custodianship
- **Steering Body**
 - IP 'ownership', approvals
- **Management Board**
 - Control, rate setting & change review
 - Regulators, Industry, Providers, Observers
- **User Group / Communities**
 - Usage, issues & requirements
 - Regulators, Industry, Observers, Medical Research Communities, Product/Service Providers
- **Providers**
 - Platform management, services delivery, service fee collection
 - Contractors

Representative Model: ICH/MedDRA Management Organization Structure 5

MedDRA MANAGEMENT BOARD:

- EMEA - European Medicines Agency [EU]
- EFPIA - European Federation of Pharmaceutical Industries & Manufacturers
- MHLW - Ministry of Health, Labour & Welfare [Japan]
- JPMA - Japan Pharmaceutical Manufacturers Association
- FDA - Food and Drug Administration [USA]
- PhRMA - Pharmaceutical Research and Manufacturers of America
- Health Canada [Canada]
- MSSO - MedDRA Maintenance & Support Services Organization [Northrop Grumman]
- JMO - Japanese MedDRA Maintenance Organization
- IFMPA - International Federation of Pharmaceutical Manufacturers & Associations

MedDRA MANAGEMENT BOARD OBSERVER

- WHO - World Health Organization

INTERFACES:

1. Infrastructure, salaries, & volunteers
2. Secretariat & Board expense coverage
3. Contracts; custodianship
4. Oversight; recommendation approval
5. Recommendations; recommendation comments; allowable service rates
6. Day-to-day contractor oversight
7. Topics of interest
8. New requirements; release distribution
9. Topics of interest



Question: What are the necessary attributes and characteristics of the third party entity or entities?

Separation of Responsibilities; Mix of Third Party Entities

- **Association**
 - Industry focus
 - Custodian of intellectual property
 - Infrastructure funding source
 - Source of volunteers
 - Contractual mechanisms
 - Ability to be an international body
- **Harmonization Entity/Steering Body**
 - Community focus
 - Not a legal entity
 - Small
 - 'Ownership' of intellectual property
 - Ability to be an international body
- **Management Board**
 - Platform focus
 - Stakeholder community representation
 - Approve changes, rates, services, development
- **User Group / Communities**
 - Issues & requirements focus
 - Users of platform; driver of new requirements
 - Mix of Not-For-Profit, For-Profit & other entities
- **Providers**
 - Development/operations focus
 - Multiple entities to maintain competition/ manage risk
 - Competitively selected
 - Large entities for continuity of services & scalability, i.e., primarily For-Profit



Question: What services could the third party entity or entities provide?

Provider Services

- Primary Provider:
 - Engineering
 - Standards Maintenance
 - Development
 - Financial Management
- Primary/Secondary Provider(s):
 - Infrastructure
 - Operations
 - Products, Services & Support
- Secondary Provider(s):
 - Certification/Audit

Platform Services

- Translation –message structure & terminology
- Information Model –facilitate inter-core communications & support international standards
- Identification / Location – given a specified set of data, identify the source location
- Message Routing – manage destination of solicited & unsolicited messages
- Auditing – maintain record of information access
- Confidentiality – security at rest & in motion, & control of access

SAFE – Signatures and Authentication for Everyone



Question: What collaborative efforts by FDA with a third party entity would be beneficial to establish services?

- Participate in review of platform requirements & certification processes
- Confirm guidance provided consistent with regulations
 - Support for other FDA regulatory functions
- Contribute requirements for platform beyond e-submissions, e.g.:
 - Participate in a National policy discussion on the return on investment for clinical trial support in the NHIN to leverage those tools, infrastructure, and standards
- Consider incentives and/or regulations to promote use



Comment Summary – IV B, Third Party Entities

<i>Issue</i>	<i>Northrop Grumman Position</i>
“Concept and feasibility of an electronic platform that would facilitate the exchange of clinical research information and other regulatory product information”	Concept demonstrably feasible
“Role of a public private partnership in the creation and assessment of such a platform”	Required for success
“Whether the functions of the platform could be assumed by a private entity or entities with the relevant technological expertise.”	Multiple entities recommended



Questions?

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