

**NORTHROP GRUMMAN**

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

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**DEFINING THE FUTURE**

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**HEALTH**

*This presentation discusses an NHIN Architecture Prototype project made possible by a contract from the Office of the National Coordinator for Health Information Technology (ONC), DHHS. The content is solely the responsibility of the authors and does not necessarily represent the official view of ONC.*



## 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

<i>Competencies</i>	<i>Successes</i>
<ul style="list-style-type: none"> <li>▪ Systems Integration and Systems Engineering</li> <li>▪ Custom development of large, complex software systems</li> <li>▪ Data management, warehousing, mining, analysis, visualization</li> <li>▪ Information security</li> <li>▪ Domain experience in health informatics, public health practice, clinical practice, medical terminology, health information privacy, and life sciences</li> </ul>	<ul style="list-style-type: none"> <li>▪ Designed and developed the largest global, enterprise-wide electronic health record (EHR) system in the world.</li> <li>▪ Pioneered the only operational nationwide health information exchange in the US.</li> <li>▪ Support development and operation of the only national public health information exchange in the world.</li> <li>▪ Contractor for only civilian health information exchange initiative in the US.</li> <li>▪ Designed and developed a unique medical terminology / ontology translation service.</li> <li>▪ Maintain &amp; distribute the MedDRA safety terminology/coding standard developed for the ICH.</li> </ul>
	<div style="display: flex; align-items: flex-start;"> <div style="margin-right: 10px;">  </div> <div> <p><b>AHLTA for DoD</b></p> <ul style="list-style-type: none"> <li>▪ &gt;7M beneficiaries</li> <li>▪ &gt;7K physicians</li> <li>▪ 81 facilities</li> </ul> </div> </div> <div style="display: flex; align-items: flex-start; margin-top: 10px;"> <div style="margin-right: 10px;">  </div> <div> <p><b>FHIE/BHIE for VA</b></p> <ul style="list-style-type: none"> <li>▪ 170+ facilities</li> <li>▪ &gt;19M personnel</li> </ul> </div> </div> <div style="display: flex; align-items: flex-start; margin-top: 10px;"> <div style="margin-right: 10px;">  </div> <div> <p><b>PHIN for CDC</b></p> <ul style="list-style-type: none"> <li>▪ prevention</li> <li>▪ detection</li> <li>▪ response</li> </ul> </div> </div> <div style="display: flex; align-items: flex-start; margin-top: 10px;"> <div style="margin-right: 10px;">  </div> <div> <p><b>NHIN for HHS</b></p> <ul style="list-style-type: none"> <li>▪ e-health records for all Americans</li> </ul> </div> </div> <div style="display: flex; align-items: flex-start; margin-top: 10px;"> <div style="margin-right: 10px;">  </div> <div> <p><b>TSB for DoD</b></p> <ul style="list-style-type: none"> <li>▪ semantic interoperability</li> </ul> </div> </div> <div style="display: flex; align-items: flex-start; margin-top: 10px;"> <div style="margin-right: 10px;">  </div> <div> <p><b>MedDRA for IFPMA</b></p> <ul style="list-style-type: none"> <li>▪ language independence</li> </ul> </div> </div>

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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.

**TSB** – Translation Service Bureau, a “service” for translating among standard and proprietary terminologies and ontologies.

**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

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

- **Multiple stakeholders (industry, regulators, medical research community, providers)**
  - Both public & private entity participation required to effectively represent all points of view
- **Different stakeholders have different needs**
  - Governance/implementation structure should promote flexibility & interoperability
- **Stakeholders are global**
  - Governance/implementation structure should allow expansion beyond U.S. region
- **Workable governance models exist for public-private partnership**
  - ICH / IFPMA / MedDRA MSSO , DHHS / ONCHIT / NHIN

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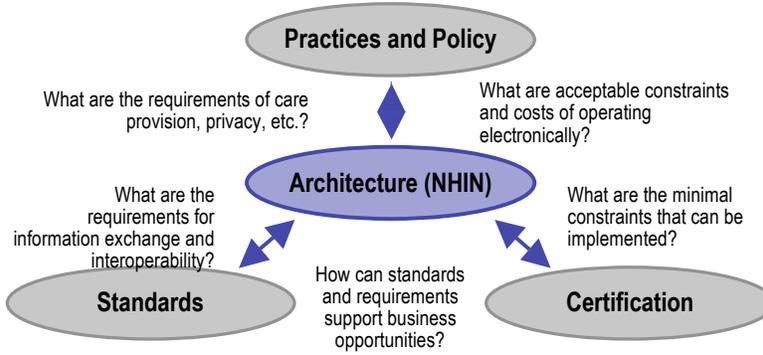
DHHS – U.S. Department of Health and Human Services

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 (MedDRA Model)
  - Similar, but not identical
- Steering Body → IP ownership
- Management Board → contracting/approval
  - Regulators, Industry, Providers, Observers
- User Group / Communities → use/comment
  - Regulators, Industry, Observers, Medical Research Communities, Product/Service Providers
- Providers → platform management/services delivery
  - Engineering
  - Standards Maintenance
  - Development
  - Infrastructure
  - Operations
  - Products, Services & Support
  - Certification

*Representative Model: MedDRA Management Organization Structure*

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#### 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



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

- Separation of Responsibilities
- Mix of Not-For-Profit and For-Profit Entities
- Steering Body → legal control of IP
  - Ownership of intellectual property
  - Ability to become an international body
- Management Board → trusted entity
  - Not-for-profit
  - Small
  - Stakeholder community representation
  - Contractual mechanisms
  - Potentially association-based
- User Group / Communities → participatory
  - Mix of Not-For-Profit & For-Profit entities
  - Users of platform
- Providers → contracted functions
  - Multiple entities to maintain competition and 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?

- Multiple for-profit entities required to supply all provider functions

<ul style="list-style-type: none"><li>• Engineering</li><li>• Standards Maintenance</li><li>• Development</li></ul>	<b>Systems Integration Services Provider</b>
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<ul style="list-style-type: none"><li>• Infrastructure</li><li>• Operations</li></ul>	<b>Managed Services Provider(s)</b>
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<ul style="list-style-type: none"><li>• Products, Services &amp; Support</li></ul>	<b>Product &amp; Consulting Services Provider(s)</b>
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<ul style="list-style-type: none"><li>• Certification/Audit</li></ul>	<b>Certification Services Provider(s)</b>
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**Question: What collaborative efforts by FDA with a third party entity would be beneficial to establish services?**

▪ **Leadership**

- Participation in National policy discussion on the return on investment to clinical trial support in the electronic health record in NHIN



## 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 required

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Questions?

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## Contact Information

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