

# An Introduction to Noblis & Our Work in Healthcare



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# Who We Are

- **A unique non-profit – unencumbered by shareholder, constituent or commercial interests**
- **Over 500 senior professionals - thought leaders and subject matter experts – a national resource in science, biomedical research, strategy and technology**
- **Headquartered in Falls Church, Virginia with offices nationwide**
- **Internal labs for both Noblis-sponsored and extramural-funded research**
- **Currently provide technology support to 37 federal agencies and 36 state governments**

# Noblis in Healthcare

## Noblis Sponsored Research (MSR)

- Focus on societal and industry issues
- Knowledge management and integration
- Knowledge dissemination
- Solution prototyping
- Research and analysis

## Technology-Based Services

- Implementation of new technology-enabled capabilities
- RASMAS – Focused on product and safety alerts
- Management of conflict of interest using knowledge management tools

## Client Services & Thought Leadership Programs

- Client Services focused on multi disciplinary services for public and private healthcare
- Thought Leadership focused on multidisciplinary issues of:
  - Phase IV Clinical Trials
  - Value Based Performance

# Technology-Based Services

## Technology-Based Services

Provide health care organizations with more effective ways of doing business through the implementation of new technology-enabled capabilities.



*Noblis Healthcare developed the Web-based service **RASMAS** that significantly enhances patient safety by improving the information, timeliness, and workflow in handling the high number of product and safety alerts that health care organizations receive – prevents patient/staff injuries, reduces costs, avoids litigation, saves lives.*

# RASMAS

- Web-based, subscription system for safety alerts (product recalls – from children’s toys to lung transplant tissue)
- ~ 6,000 users in over 300 healthcare facilities
- Efficient, workflow management, closed-loop system (requires response)
- Noblis provides FDA with data on all recalls
- Rapidly growing system with increasing functionality for tracking process

# Noblis Focus on Phase IV Clinical Trials

# The Problem

IOM Report “The future of drug safety: promoting and protecting the health of the public” (National Academies Press, 2006 <http://www.iom.edu/CMS/3793/26341/37329.aspx>)

- *Improve post-marketing surveillance (Psaty BM, Burke SP. N Engl J Med 2006;355:1753)*
- *Enhancing Drug Safety and Innovation Act (S. 3807/Kennedy/Enzi bill) introduced to the Senate 08/03/06 – emphasizes “life-cycle” approach to drug regulation; Enzi/Kennedy hearing with Chair of IOM Committee 11/16/06; Bill re-introduced 02/01/07*
  - **“Risk and Evaluation and Mitigation Strategy” for drug safety**
  - **Reagan-Udall Institute for Applied Biomedical Research at FDA**
  - **Clinical trials registry and results database (public access)**
  - **Reform of conflicts of interests on FDA advisory committees**

# Some of the obstacles...

- Less than 10% of mandated trials performed (FDA data, 2005)
  - FDA needs more regulatory power to enforce (S.3807)
- Phase IV trials usually managed by industry as *marketing* effort (not science-driven)
- Difficulties in obtaining data
  - Logistics
  - Participation by physicians and patients
  - Electronic health record (EHR) not universally adopted or adapted to mine essential data
- Underfunded, understaffed FDA for post-licensing surveillance
- Inadequate, underused, user-unfriendly surveillance system
- Unrealistic expectations by public regarding new drugs, devices
- Lack of carrot or stick for industry to invest in Phase IV trials

# Possible Next Steps.....

*Noblis is in the discovery phase of determining how to apply our extensive experience and capabilities to the development of a new .....*

## ***Phase IV Clinical Trails System***

- *Post-licensing surveillance (e.g. RASMAS) - ? Adaptable platform*
- *Electronic health records and quality of care measures*
- *Knowledge management tools needed to detect both low-incidence toxicity and higher frequency events superimposed on a high background (e.g. the Vioxx story); also can be used to mine for conflicts of interest for review panels*
- *Design and implementation of clinical trials that can work in the community*
- *Excellent working relationships across Federal Health Agencies (e.g. CMS; VA; DoD; CDC; NIH, etc.) as well as with private industry (e.g. Pharmaceutical manufacturers, PBMs, Health Plans, etc.)*