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Business Case Breakout Session

Paris, September 2006

Ed Dzwill and Hugh Lockhart

The global language of business

www.gs1.org

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Business Case - Overview

Objective	The Business Case for Global Data Standards in the Healthcare Supply Chain
Mission	Develop guidance for global healthcare on effective utilization and development of global standards with the primary focus of automatic identification to improve patient safety
Target Global Audience	Manufacturers, Distributors, Hospitals, Pharmacies, Regulatory Agencies, Trade Groups, Certification Bodies
Implementation	Multiple Phases through a HUG partnership with Michigan State University. Delivery of completed Business Case January 2007.

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Current HUG Business Case Team

- Ed Dzwill – Lead – J&J Pharma
- Michigan State University
- Massimiliano Molinari – J&J Pharma (Janssen Cilag)
- Josef Simacek – Pharm Data
- Christian Lovis – University Hospital of Geneva
- Peter Arakelian – Amgen
- Uwe Klaner – Baxter Europe
- Eduardo Rodriguez – GS1 Chile
- Scott Cameron – Novartis
- Gary Clement – Kimberly Clark
- Dr. Bruce Anderson – New Zealand Ministry of Health
- GS1 HUG™ Leadership Team
- Jay Crowley - FDA

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MSU School of Packaging Background

- Since 1952, MSU School of Packaging has conferred 5,600 BS, MS, and PhD degrees. Currently 500 undergraduate, 60 graduate students, and 16 full time faculty
- Yearly 200 students achieve Bachelor Degrees, 15 Masters Degrees, 5 Ph.D's
- Cooperative Education program exists with companies in many industries
- Bachelor of Science are generalists, with broad knowledge in materials, processes, and design considerations with skills applicable to many industries
- Master's of Science are specialists with stronger analytical, technical skills additional graduate level research with expertise in a specific area of packaging

Michigan State University Core Team:

	Role	Title	Expertise
Dr. Hugh Lockhart	Project Director	Professor	Drug, Device Packaging, Regulatory Impacts
Dr. Robb Clark	Collaborator	Associate Professor	Automatic Identification Systems, both printed codes and RFID
Dr. Laura Bix	Collaborator	Assistant Professor	Healthcare, Consumer Interface, Drug, Device Regulatory Impacts
Dr. Diana Twede	Collaborator	Associate Professor	Supply Chain, Logistics, Economics
Dr. Harold Hughes	Collaborator	Professor	Computer Management Systems
John Spink	Project Manager	PhD Candidate	Anti-counterfeit systems, Project Management, Business Management

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MSU Partial List of Collaborating Faculty

- Eli Broad College of Business, Cheryl Speier, Assoc Dean
- National Food Safety and Toxicology Center, Edward Mather, Director
- College of Law, Peter Yu, Associate Professor
- School of Criminal Justice, Robyn Mace, Specialist
- College of Veterinary Medicine, Monte Reimers, Dir of QA
- Department of Computer Science and Engineering, Dean Aslam, Professor
- Gast Business Library, MSU Libraries, Kara J. Gust, Librarian

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MSU Business Case Deliverables

- Deliverables:
  - Detailed position paper of approximately 125 pages
  - PowerPoint Executive Summary of 10 pages
  - PowerPoint conference presentation of 25 pages
- Planned to be a fifteen week effort
- Other Impacts:
  - Research done by MSU faculty will increase knowledge in global Auto Identification
  - Students will be better prepared for the global environment in Auto Identification
  - Research will create a center of excellence at MSU for new areas of study

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School of Packaging

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MSU Business Case Methodology

- Student researchers recruited from 6 contributing departments
- Training for 1 week with students from each school
- Students trained in the assumptions, purpose, background, and literature search methodology
- Students to have a starter set of key words, phrases and will be supervised by collaborating faculty
- Literature search to assure information is relevant with agreeing and opposing views
- Teams will meet twice weekly to report, share, modify methods as needed
- GS1 HUG™ Business Case Team will review progress and direction
- Stakeholders will be contacted using telephone, e-mail, or face-to-face interview
- Researchers may contact academic colleagues globally

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Student Researchers

- 15 Students (12 Packaging, 3 Supply Chain Management)
- 3 are Juniors, 9 are Seniors, 3 are Graduate Students
- Work experiences – 8 in drugs and devices, 3 in food, 2 in paper and paperboard, 4 in mfg and chemistry
- Student nationality/ethnicity: U.S., India, China, Japan, Korea

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Auto ID SCM Training

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Automatic Identification

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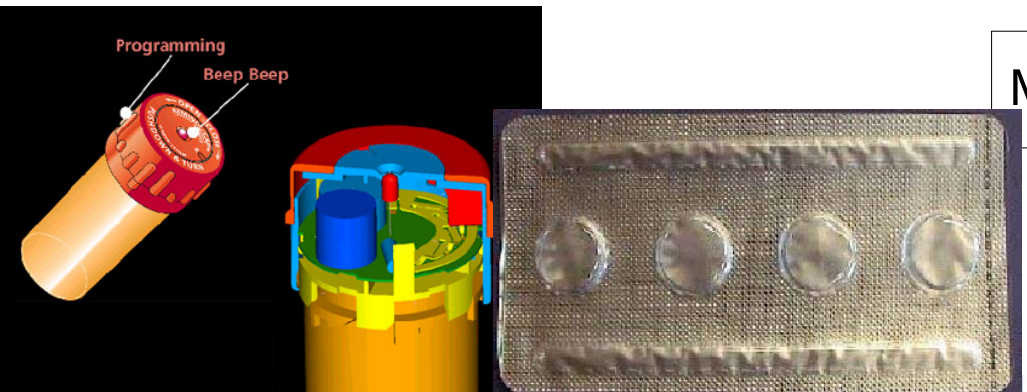
MSU School of Packaging

September 16, 2006

Automatic Identification and Data Capture



Voice & Vision Systems

2D Bar Codes

OCR

AIDC

Bar Codes

Biometrics

RFID

Card Technologies

Magnetic Stripe

Smart Card

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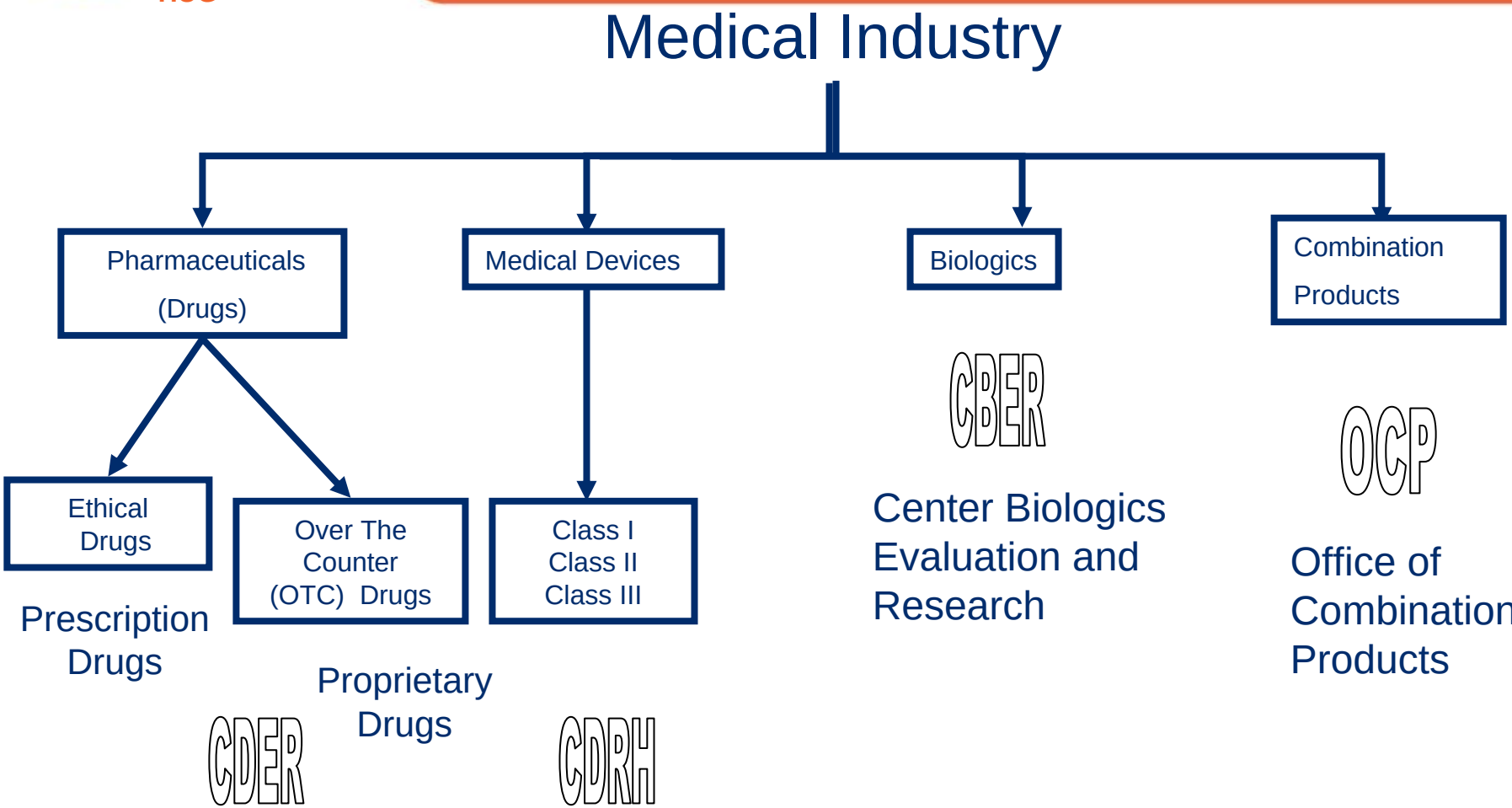
Healthcare Training

For Presentation
to the GS1 HUG™ student working group
September 10, 2006
By Laura Bix
And John Spink

Overview of Healthcare Industry



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At the MSU Library

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For EndNotes Training

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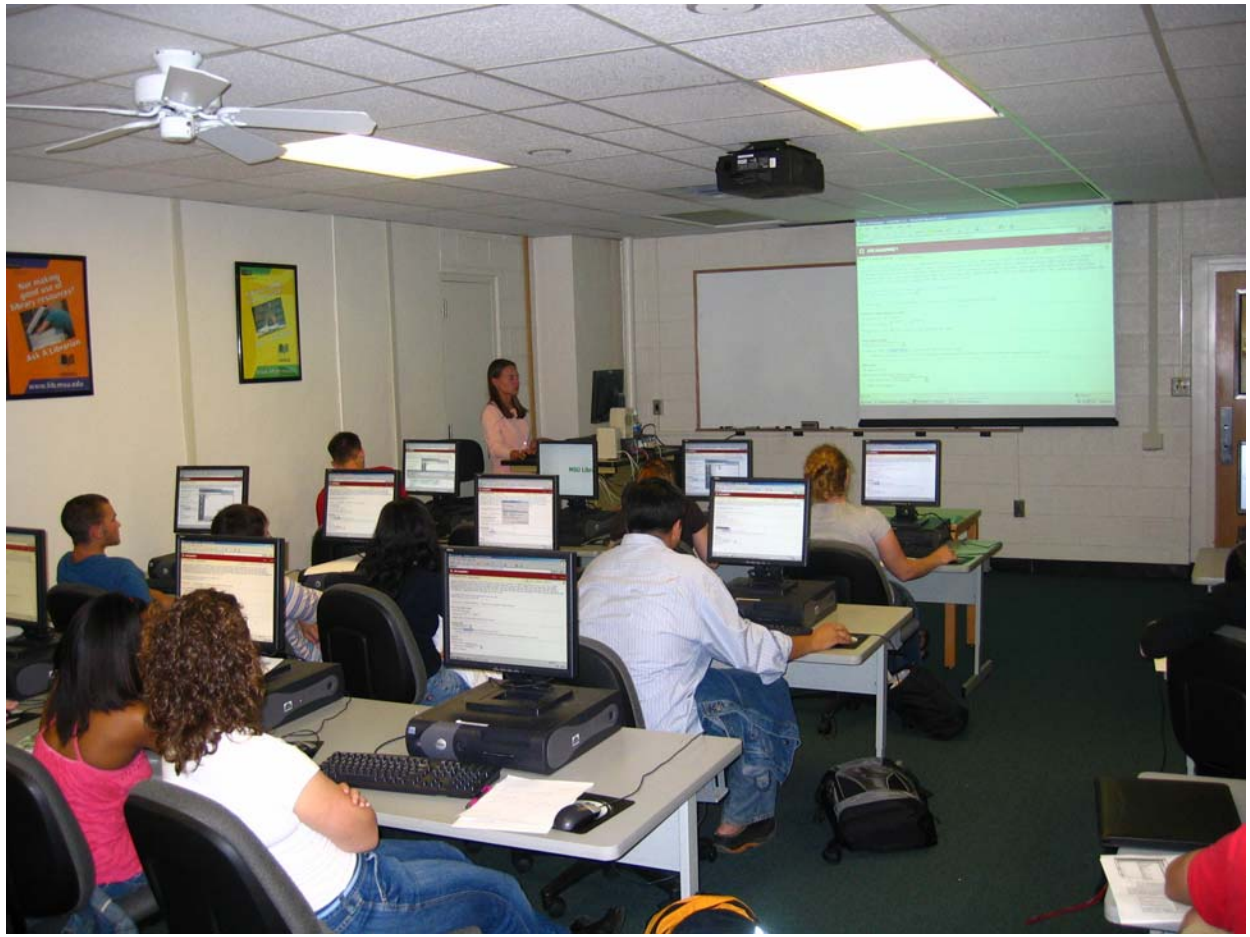
EndNotes Training Session



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MSU Working Groups

- Analysis of Data Collected by GS1 HUG™
  (The Doc HUG Team)
- Literature and Data on Ramifications for Public Health
  (The Carnage Team)
- Literature and Data on Economic and Business Ramifications
  (The Auto SCM Team)
- Synthesis
  (The Syn Team)

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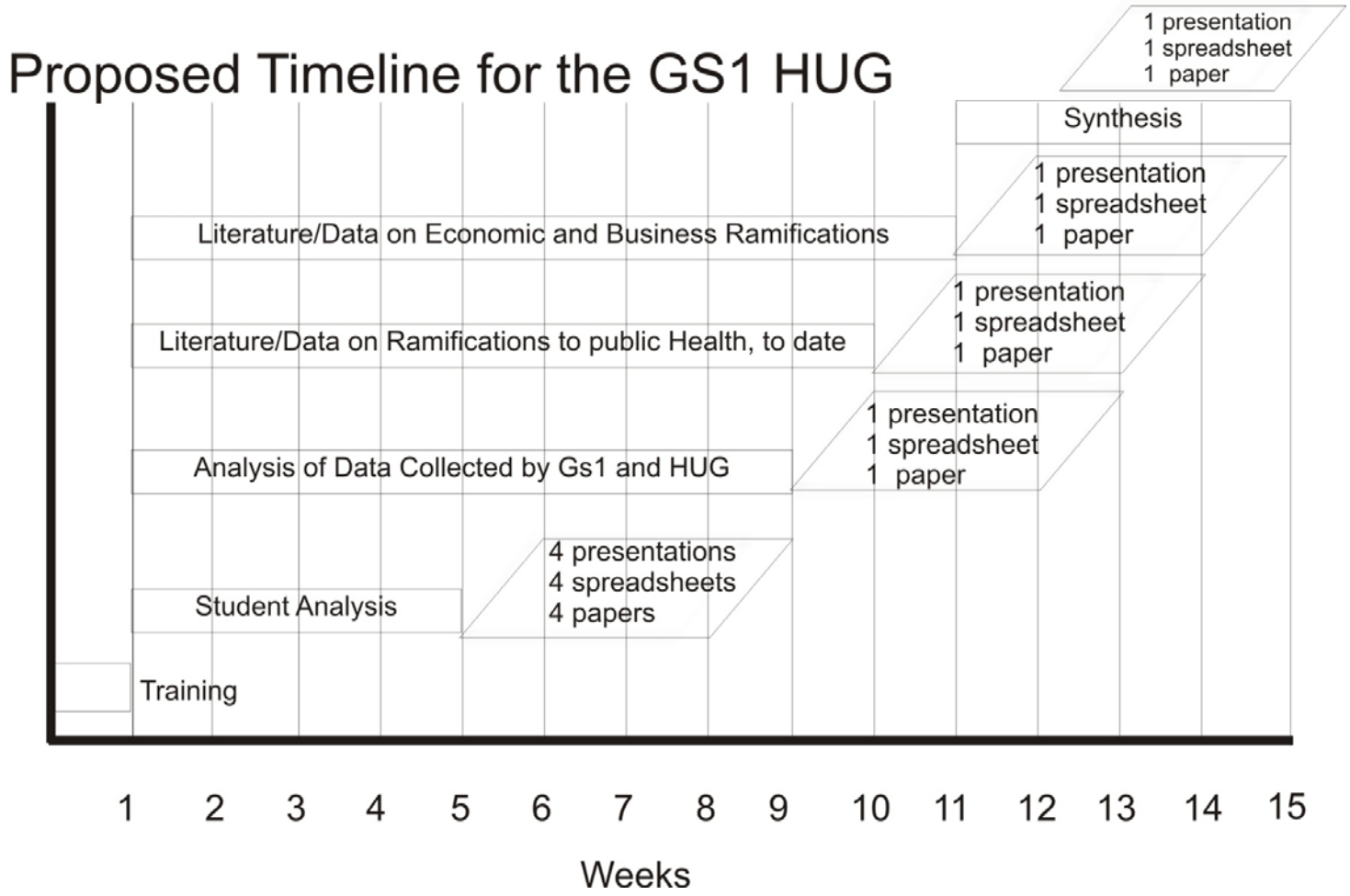
MSU Business Case Proposal Timeline



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The Work Plan

1. Train all student researchers in
   a) Purpose of project and GS1 mission
   b) Healthcare and regulatory terminology
   c) Supply chain terminology
   d) Use of EndNotes software

2. All teams will
   a) Review literature and GS1 team reports starting with key words
   b) Summarize each item found
   c) Meet at least weekly to evaluate and summarize all information found
   d) Write summary for later use in final report

3. Synthesis team will meld the summaries, design and write the final report

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Database Resources

- **Pub Med** – U.S. National Library of Medicine; citations from MED -LINE and life sciences journals
- **MEDLINE** – Health and Medical Journals and other news sources
- **ABI/INFORM** – Business, management, economics
- **ProQuest** – Information and learning, a broad range of journals and periodicals
- **LexisNexis** – legal, business, academic, government and public records
- **Pira** – packaging and related journals and news sources

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Data Base Tools

- **EndNotes** – a software tool for managing and publishing bibliographies. Use for organizing references and for summarizing references

- **Angel** – an MSU campus-wide network in which we have a private group domain. We will be able to share documents freely among the MSU team members

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Key Assumptions = Key Hypotheses

- The Business Case will identify whether or not there exist serious health risks and business ramifications which standardization of unique identifiers and automatic identification can ameliorate.
- The Business Case will explore whether or not a common standard for serialized codes is best suited for automatic identification.
- Healthcare products require the ability to be uniquely and automatically identified.
- The Business Case will be a presentation to the stakeholders of the costs, risks, and benefits of a single global standard for unique and automatic identification

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Key Assumptions = Key Hypotheses

- The stakeholders include manufacturers, distributors, wholesalers, hospitals, retail pharmacies, third party payers, healthcare professionals, regulators, consumers and technical solution providers.
- Information on costs, risks, benefits and predicted adoption time-frames is being gathered by other operating groups within GS1 HUG™, and we will draw on the reports they are filing
- Information on costs, risks, benefits and predicted adoption time-frames is available from literature available through various data bases
- Literature search will include trade press, peer reviewed journals, electronic sources, business and medical journals, such widely known data bases as Medline, Proquest, Lexis-Nexis, Pira, GPO Access

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Key Assumptions = Key Hypotheses

- Automatic identification is essential to authentication and serialization, both of which have applications that are international in nature
- Automatic identification and mass serialization are unique outcomes that will be optimized if they have an integrated, interactive solution - all systems can communicate with each other.
- The findings of the project will be in terms of death and detrimental health risks as well as costs and benefits for consumers, manufacturers, distributors, hospitals, pharmacies, regulatory agencies, trade groups, certification bodies, etc

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Key Assumptions = Key Hypotheses

- These are inherent benefits related to having a global data standard and interactive solutions
- Avoid incorrect medication
- Avoid incorrect dosage
- Automatic identification of recalls at point of use or point of sale
- Identification of product authenticity (counterfeit), including utilizing the data to validate chain-of-custody to identify and prosecute counterfeiters
- Identify expired or damaged product
- Protection from risky supply chains (diversion, gray market)
- Automated invoicing and supply verification - assists healthcare providers and practitioners from bedside to storage to procurement with respect to authorized use, inventory, re-orders, billing, fraudulent use patterns, credits and supply chain management
- Reduction of consumer health risk

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Key Assumptions = Key Hypotheses

- The Business Case will identify technology solutions (including associated implementation time-frame, cost and solutions), but not recommend a specific solution - review of solutions is underway by various working groups in GS1 and are being reported elsewhere
- Current trends in global regulatory activity will be covered
- MSU will involve global academia as a result of what we find in information collected by other working groups of GS1 and by literature search and interview. As other academic organizations are identified, their input will be solicited.

Business Case Phases

- Phase 1- Overview and Proposal - Completed
  - GS1 HUG™ requested the proposal be divided into separately funded phases
- Phase 2 - Business Case Overview - Sept 2006 Paris Meeting
  - A progress report on faculty and GS1 HUG™ research
- Phase 3 - Expanded Primary Research - January 2007 Berlin Meeting
  - Open source and primary research based on findings. Expand to international interviews in other primary research
- Phase 4 – Expanded Solutions and Benefits - June 2007
  - Expand open source and primary research based on findings. Expand to potential solutions, associated costs, benefits, review future trends in regulations on a worldwide basis.

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We Will Use Reports from These HUG Work Teams

- Standards Implementation/Regulatory Affairs
- Communication and Coordination
- Vaccines and Biologicals
- Instruments and Implants
- Standards Development
- GTIN Allocation Rules

We Need 3 Things from You

- Reports from the GS1 HUG™ Work Teams
- Your favorite data base other than those listed
- Your favorite key words for searching your literature

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Contact Details

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