HUG

Vaccines and Biologics Work group June 2006 HUG MEETING

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The global language of business

www.gs1.org

GS1 Vaccines and Biologicals Workgroup

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Problem Statement

We lack a global data standard (elements and carrier) for vaccine and biological products.

The lack of a global standard presents a barrier to adoption and a barrier to infrastructure development.

The lack of a global standard facilitates divergent individual country/market requirements.

The lack of a global standard drives risk across the entire supply chain (medication/transcription errors)

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VACCINE/BIO Workgroup Strategy

Leverage the common elements with pharma as much as possible

Identify key differences for vaccine and Bio products and place in an appendix

- RF Energy concern
- Cold chain requirements
- Government providers
- Specialty clinic applications
- Unique patient lifetime record keeping requirement
  (need to be permanent and transferable)

RF Energy Concern

- Workgroup does not think that RFID is a good short term solution for vaccine and BIO products at item level (heat generated from item level tagging)
- Workgroup feels that 2D barcodes could be an efficient item level identification solution
- FDA is currently testing some products (Biological?)
  - Electromagnetic RF energy testing
  - Unclear what the FDA will do with the data
  - Additional data may be required
- Opportunity to leverage the HUG as a focal point with the FDA conversations
  - HUG To develop letter to Regulatory Agencies?
- EPC GLOBAL driving HF Vs UHF debate
  - Potential to deflect to EPCGLOBAL

Cold Chain Requirements

Integrate cold chain conditions in testing of tags and barcodes to EPC GLOBAL (example; impact of frost layer)

Opportunity to develop a standard for a smart chip to monitor T leverage EPCGLOBAL class 4 tags ?

Opportunity to develop a standard for a barcode that is T sensitive

Opportunity to develop standards for vaccine vial monitors

Need for knowledgeable and trained supply chain partners to participate in the HUG

Government Providers

Governments are key customers in this segment

Workgroup to assess impact this week

Specialty Clinic applications

Unique distribution and supply chain Vs Pharma

Workgroup to assess impact this week

Unique Patient Lifetime record keeping

What is the customer need ?

National and International groups first – Lisa has some contacts

Look at tender requests – each manufacturers

What data is important

- NDC
- Generic name
- Manufacturer
- Lot and expiry
- Name of administer

What data format? Need for multipart labels?

CDC harmonization ? VISI standards ?

Canada meeting being organized with manufacturers. Opportunity for HUG to drive globally. Summer time or September

Voice of Customer Details

Drs, Nurses, OB/GYN, General Practitioners, pediatrician

Governments, NIH-UK, MOH-Canada

CDC

NGO

Military

WHO, UNICEF, GATES foundation,

Wholesalers

Specialty clinics (hemophiliacs)

CVS type clinics (For Flu administration)

Company nursing departments

Patients

Key Objectives for this week

Continue to detail the major differences between Bio/Vaccine and PhRMA

Determine next steps (if applicable) for the workgroup

- Is highlighting/recording the key differences enough?

There is a lack of supply chain partnership on the workgroup

- We need your help to continue.

HUG
Vaccine/Biological
Workgroup

Contact details

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Customer Details

VOC Process

How do we collect the data?

Face to face, phone, email?

Who will collect the data?

Do we share the data ?

If so, with who?

How will we use the data?

Voice of the Customer

What machine readable data is most important to impact patient safety and reduce medication errors?

Is there any additional machine readable data provides value?

Are you currently utilizing any machine readable data?

If so, how do you acquire the data?

If so, what data is used and how do you utilize the data?

Do you have plans to increase your use of machine readable data?
If so, how and what are your plans?

Are there any best practice examples that you can reference?

Do you read bar codes now? Any plans

Are you capable or reading 2D bar codes? Any plans?

Are you capable of reading RFID tags? Any plans?

Voice of the Customer

If a manufacturer were to include additional machine readable data elements would that provide any business benefit? If so, please describe.

If manufacturers were to include additional machine readable data elements would you invest in the technology to read this data?

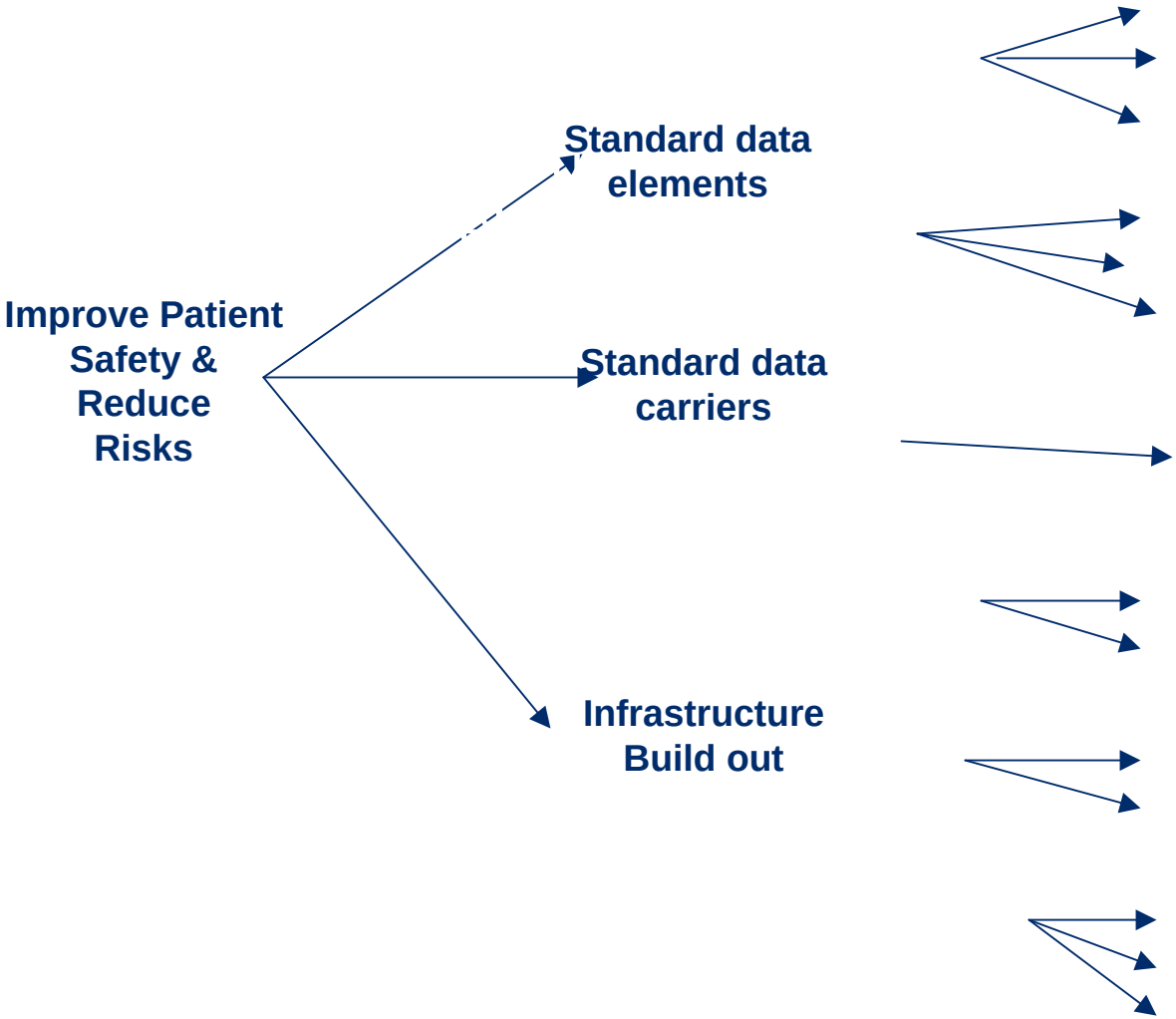
Do you see benefit in a global standard?

Would you be interesting in participating in the standard setting process?

WHY

WHAT

HOW



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Workgroup Attendees – May 8 call

Peter Tomicki - Baxter

Peter Eves – GS1 - UK

Lisa Belzak - CIDPC

Bruce Cohen - GSK

Steve Hess - Merck

May 8 notes and Action Items

Need to engage the team and our supply chain partners

Mike Megan – DHL formally part of Excell – Peter Eves to follow up
UK DOG tracking group – Peter Eves to follow up
Immunization registry in the US – Lisa has some contact
CDC – Bruce Wenninger – Steve to follow up
Christian Blouin – Merck contact in Montreal – Steve to follow up
Bruce will contact the GSK rep in Canada