Implementation of GS1 standards in clinical trials processes

Welcome!
Our experts, sharing their experiences...

- Chaired by Dr. Greg Koski, PhD, MD, Chairman of the Board of Directors, Co-Founder & President, CEO, ACRES - Alliance for Clinical Research Excellence and Safety, U.S.

- Mr. Hans von Steiger, PMP Group Leader, Clinical Supply Chain Management, Pfizer, U.S.

- Ms. Sylvia Bartel, VP Pharmacy, Dana-Farber Cancer Institute, U.S.

- Mr. Sylvain Alberola, Head, Clinical Supply Chain Industrial Development, Sanofi
Today’s agenda

• 10 min intro – Greg
• 15 min presentation – Hans
• 15 min presentation – Sylvia
• 15 min presentation – Sylvain
• 30 min Q & A – Facilitated by Greg
• 5 min close - Greg

Please be ready with your questions!
Standards—an Essential Systems Building Block

Global GS1 Healthcare Conference
17-19 October 2017 | Chicago, U.S.

Safer, more efficient care starts with a simple scan.
Our Goal:

To improve the human condition through application of “systems thinking” to transform health care and research

• Reunite clinical care with research
• Enable and promote collaboration
• Accelerate discovery and translation
• Enhance knowledge, quality and safety
• Improve health and quality of life

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Silos: An Impediment to System Building

People

Technology

Processes
The Power of Integration: Connectivity and Interoperability
The Power of Integration: Creating Synergy

People

Technology

Processes

SYNERGY

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Integrated Systems: Realizing the Synergy of the Whole
A World View of the Clinical Trials Process from the Perspective of a Research Site

- Review and Accept Protocol
- IRB Submission and Reporting
- Monitoring and Audits
- Adverse Event Reporting and Management
- Data Management
- Conduct the Study
- Recruitment and Enrollment
- Training and Preparation
- Research Team

- Regulators
- Technologies
- IRB/EC and Ancillary Approvals
- CROs
- Patients
- Physicians, Families and Friends
- Service Providers and Logistics
- Sponsors
- Financial Management

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Smart Systems for Performance Enhancement and Quality Management

Inputs — Processes — Outputs

Smart Sensors

Rules — Standards — Logic

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ACRES System Overview

Global Site Network
- Study Sites
  - Site Director
  - Investigators
- Standards
- Information Systems
  - EDC
  - CTMS
  - Risk Monitor
  - Operations Dashboard
- Compliance
  - Research Integrity
  - Patient Engagement
  - Logistics Manager
  - Nurse and Technicians
  - Data Managers

Healthcare Organizations
- Electronic Health Data
- Patient Demographics

Industry Sponsors
- Pharmaceuticals
- Biotechnology
- Medical Devices

Contract Research Organizations
- Site Management Organizations

Universal Collaborative Interface
Cloud-based Enterprise Data Vault
Secure Data Aggregation and Exchange
Artificial Intelligence
Integrated Technology
- Analytic Engines

Data Services
- Clinical Data
- Operational Data
- Metadata Library
- Safety Data
- Financial Data

Federated Trust Framework
Identity Management
Secure Digital Transactions
E-Commerce

Supply Chain Providers
Integrates Logistics

Ethics Review Boards

Regulatory Oversight Agencies
- Smart Monitoring
- Smart Financial Engine
- Real-Time Pharmacovigilance
- Smart Auditing
--building a global collaborative system for clinical research excellence, together!

http://www.acresglobal.net
GS1 Implementation for Clinical Trial Supplies

Pfizer Clinical Supply Mobile App Case Study
- Highlight the Challenges Due to Lack of Standards

Hans von Steiger, Pfizer Inc.
18-Oct-17
Topics

• Kit Verify App Overview
• Contract Vendor Challenges
• Distribution System Challenges
• Interim Solution
• Three Horizon Vision
Kit Verify App

Android & iOS verification mobile application for use with *Pfizer’s IRT System*

Originally launched in 2013 as POC

Version 2.0.0 is available now for **US market only**
Kit Verify App

Print the Drug Assignment Confirmation Report.

Scan the 2D bar code.
Kit Verify App

Scan the 2D container bar code.
Kit Verify: non-GS1 Compliant Barcode

Kit verify barcode content

- Kits are dispensed based on protocol number plus kit ID
- Neither alone is a unique identifier
- Kit verify needs a barcode with both protocol number and kit ID

Protocol Num. – B4801010
Kit ID – 35056

B4801010, 35056
Vendor Compatibility Challenges

**Vendor 1**
- WIP has a barcode on the label with kit ID only.
- Internal inventory system uses the barcode to advance WIP from one operation to the next.
- If system scanners see anything other than a valid kit ID, wrong part number designation is thrown.

**Vendor 2**
- Receive the container list from customers in a comma separated data file.
- Container list has the data printed as variable text on labels, e.g., kit ID.
- Because the Kit Verify barcode content is variable text, it needs to be sent in the CSV.
- Unfortunately, Kit Verify barcodes have commas and this is problematic for CSVs.
Clinical Supply Distribution System (CSDS)
Interim Solution

No choice but to go with 2 barcodes.

- Confusing to site staff.
- A problem on syringe labels (lack of real-estate).
Three Horizon Vision

- Build GS1 compatibility into internal systems (new CTSM)
- Manufacture and distribution vendor GS1 compatibility
- Leverage electronic data interchange (looking beyond the barcode)
Thank you
Contact Information

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Clinical Supply Chain Strategy and Management

**Pfizer Inc. – New York**

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Dana-Farber Cancer Institute’s Investigational Drug Services Processes

Dana-Farber Cancer Institute Investigational Pharmacy
Caroline Harvey, RPh, M.S
Research Pharmacy Manager
Sylvia Bartel, RPh, MHP
Vice President, Pharmacy

October 18, 2017
Disclosures

• The presenter reports no financial relationships relevant to this presentation.
Objectives

- Discuss Dana-Farber Cancer Institute (DFCI) investigational drug service (IDS) receiving workflow.

- Describe challenges with managing investigational drug inventory.

- Identify what clinical sites would need from pharmaceutical sponsors regarding GS1 standards & investigational drugs.
Dana-Farber Cancer Institute

- Founding member of the Dana-Farber/Harvard Cancer Center (DF/HCC), a federally designated comprehensive cancer care center.

- Federally designated center for AIDS Research.

- Joint programs with other Boston institutes affiliated with Harvard Medical School, Boston Children’s Hospital, and the Partners Healthcare System including Brigham and Women’s Hospital (BWH) and Mass General Hospital.
Demographics

- Clinic practice organized by Disease Center in Longwood campus (Adult-13), (Pediatric-3)

- Volume – Adult Ambulatory
  - Exam – 321,900 visits
  - Infusion – 157,533 visits

- Volume – Pediatric
  - Exam – 12,542 visits
  - Infusion – 8,238 visits
Pharmacy Statistics

- ~490,000 total dispenses / year
  - ~147,000 chemotherapy agents
  - ~343,000 non-chemotherapy agents
  - ~183,000 investigational drug dispenses
- OPD Retail Pharmacy
  - ~75,000 dispenses / year
- ~750 active drug studies
- ~1200 different individual investigational drug line items
Receiving

- Investigational products are entered into electronic inventory system upon receiving shipment.

- A unique and internal DFCI generated barcode is automatically created.

- Barcode is placed on each individual product.
DFCI IDS-2-D Data Matrix Barcode

- Drug Name
- Drug Strength
- Drug Formulation
- Lot Number
- Bottle # or Vial # (if applicable)
- Custom NDC # (assigned by DFCI)
- DFCI IRB Number of the Clinical trial
DFCI IDS-2-D Data Matrix Barcode

- Does **NOT** contain **expiration dates**
  - Are tracked in our electronic inventory system.
  - Expiration dates may be subject to change via extension memos.
Investigational Drug Receipt Example

Contents of Order

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Description</th>
<th>Material Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>12</td>
<td>Bottle for 25mg</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Bottle for 100mg</td>
<td></td>
</tr>
</tbody>
</table>

Material in Material Number Order

- 20119758
- 20119760
- 20119761
- 20119764
- 20119766
- 20119767
- 20119773
- 20119775
- 20119778
- 20119780
- 20119781
- 20119784
- 31082075
- 31082078
- 31082079

Packing Instructions:

- Store refrigerated at 2 to 8°C (36 to 46°F). Do not freeze.
- Store at Controlled Room Temperature
Investigational Drug Label Example

Example of commercial vs. IND labeling
Why Does DFCI IDS Barcode?

- Patient safety

- Look a-like investigational drug names (ex: PF-02341066 & PF-06463922) without distinguishing generic names

- Investigational drug labeling typically a white label with small black letters & numbers

- Most investigational drugs do not contain bar codes
  - If they do, bar codes are in varying formats depending on which pharmaceutical sponsor

- Omit the need for manual transcription of drug accountability logs
Challenges of DFCI Bar Coding Process

- Manual & time consuming
- Risk of numeric transposition errors
What Do We Need From Pharma Regarding GS1 Standards & Investigational Drugs?

- A universal formatted type of bar code across all sponsors.

- Bar code that would incorporate the GS1 standards that could be used for both commercial and investigational drugs.
Why Do We Need GS1 Standards for Investigational Drugs?

- Eliminate the need for clinical sites to have a bar code scanner from each sponsor.
- Eliminate the need for clinical sites to do their own manual process of bar coding of investigational drugs.
- Increase patient safety related to the receiving and dispensing of investigational drugs.
- Improve operational efficiency.
- Improve inventory management.
“Improvement of safety in health care and the continuous reduction of error depend on the design and re-design of our systems of work”.

Donald Berwick, M.D.
Former Administrator
Center for Medicare and Medicaid Services
Former President and CEO,
Institute for Healthcare Improvement
GS1 Datamatrix
A standard for clinical trials

Sylvain Alberola, Head of Industrial Development, Clinical Supply Chain, Sanofi
Pierre Fernandez-Barbereau, Project Management, Clinical Supply Chain, Sanofi
October 18th 2017
What are we going to talk about?

• Clinical trials challenges
• Today’s situation
• What we should have and why
• A standard for tomorrow

October 18
Clinical trials challenges
Clinical trials challenges
Specific context

An Investigational Product (IP) is unique. One IP means one patient.

When we are in a doubled blinded situation, it could be a placebo, an active product or a comparator. You cannot differentiate them!

→ Special need to identify, track and trace IPs all along the chain.
Clinical trials challenges
Supply Chain

From production to patient (simplified view)

Packaging
- Quality Controls
  (Printed label controls, synchronization, completion of batches)

Distribution
- Shipments preparation
  (Warehouse and stock management)

Site
- IRT interactions
  (Allocation, Return, Accountability, Reconciliation, Destruction)

Patient
- Information, help
  (Direct To Patient)
- Devices interaction
Today’s Situation
(or how to ease our work)
Today’s situation
Sanofi (quite common situation)

Implementation of a Sanofi GS1 “like” 2D barcode in 2009.
→ Only used by sanofi and few partners

Packaging
Sanofi: GS1 “like” datamatrix
Partners: Specific solutions

Distribution
Handwriting, Excel, IRT Web access

Site

Patient

Well…
Today’s situation
Let’s take an example

An example

Study Number
EFV12345
Batch number
00001
Treatment Number
T000093
Use By End
05-2018

Corresponding Labels

Pharma Lab A
EFV12345
Batch #: 00001
Treatment #: T000093
Use by end: 05-2018

Pharma Lab B
Study #: EFV12345
Batch nb: 00001
Treat.: T000093
UBE: 05/2018

Sub contractor X
EFV12345
Pckg #: 00001
Treatment : T000093
Expiry Date: 05-2018

Within barcodes (if any)

(REF) EFV12345
(BATCH) 00001
(TREAT) T000093
(UBE) 05-2018

EFV12345;
Lot: 00001;
Treat. Nb: T000093;
UBE: 05/2018

1234567890
What we should have
(or probably the right way to do it)
What we should have
A common standard: GS1

Our example

Study Number
EFV12345
Batch number
00001
Treatment Number
T000093
Use By End
05-2018

One common way

Outer packaging

(01)ID
(240)EFV12345
(10)00001
(21)T000093
(17)05/2018

Inner packaging

(8006)ID and Rank #
(240)EFV12345
(21)T000093
(17)05/2018

Proposal (in collaboration with GS1 - Valérie Marchand)
What we should have
A common standard: GS1 Datamatrix

An interoperable standard widely known and used by all stakeholders to cover the whole chain: Real GS1 DataMatrix

One GS1 DataMatrix to rule them all
## GS1 Proposal, details

(GS1 Contact: Valérie Marchand - valerie.marchand@gs1fr.org)

<table>
<thead>
<tr>
<th>GS1 AI</th>
<th>What’s in there</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outer level (Kit Level)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(01) GTIN-14</td>
<td>Prefix + Kit Type + Check digit</td>
<td>03607980000012</td>
</tr>
<tr>
<td>(240) Additional ID</td>
<td>Study Number</td>
<td>EFV12345</td>
</tr>
<tr>
<td>(21) SN</td>
<td>Treatment Number</td>
<td>T000093</td>
</tr>
<tr>
<td>(10) Batch/Lot</td>
<td>Batch Number</td>
<td>000001</td>
</tr>
<tr>
<td>(17) Expiration date (YYMMDD)</td>
<td>Expiration Date (Not used today)</td>
<td>181005</td>
</tr>
<tr>
<td><strong>Inner level (element in the Kit)</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(8006) GCTIN, ID of the component of a trade item</td>
<td>For each element in the kit Prefix + Kit Type + Check digit + Rank</td>
<td>036079800000120106 (syringe 1 of 6)</td>
</tr>
<tr>
<td>(21) SN</td>
<td>Treatment Number</td>
<td>T000093</td>
</tr>
<tr>
<td>(17) Expiration date (YYMMDD)</td>
<td>Expiration Date (Not used today)</td>
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</tr>
<tr>
<td>(240) Additional ID</td>
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</tr>
</tbody>
</table>
So, why we should have it?
(yes, why?)
### Why we should have it

#### Benefits

<table>
<thead>
<tr>
<th>Packaging</th>
<th>Distribution</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Camera control automation</td>
<td>- Simplified common identification &amp; tracking</td>
</tr>
<tr>
<td>- Synchronization between levels of packaging</td>
<td>- Depots automation</td>
</tr>
<tr>
<td>- Improve chain with partners</td>
<td>- Late stage customization easiness</td>
</tr>
<tr>
<td>- Overall quality increase</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Investigational site</th>
<th>Patient</th>
</tr>
</thead>
<tbody>
<tr>
<td>- A unique automated way to manage kits (hand-writing)</td>
<td>- Safety !</td>
</tr>
<tr>
<td>- Overall risk and workload decrease</td>
<td>- Additional services (online information &amp; help, community)</td>
</tr>
<tr>
<td>- Global traceability improvement</td>
<td>- Devices interactions</td>
</tr>
</tbody>
</table>

© GS1 2017
A standard for tomorrow

A standard GS1 DataMatrix for clinical trials has to be widely implemented in all information systems to be really useful: Pharma labs, contractors, depots, hospitals, patients apps, ...

Let’s work together for a common standard to ease the whole process, improve quality, reduce risk and workload!
Thank you
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Questions from the audience
Please remember...

• Take a copy of the GS1 US report: Laying the Foundation Today for Tomorrow’s Innovations

• Collaboration to drive use of global standards in clinical trials processes
Networking Dinner tonight at 7:00 pm

John G. Shedd Aquarium
1200 S Lake Shore Dr.
Chicago, IL 60605

Meet in the main lobby for shuttle bus departure: 6:30 pm

Return shuttle buses: beginning 8:00 pm until 10:15 pm, running on a loop between locations

Dress code: business casual.

Please wear your event badge 😊
Thank you for your attention!