The Global Language of Business

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!

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Alliance for Clinical Research Excellence and Safety

Standards—an Essential Systems Building Block

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Alliance for Clinical Research Excellence and Safety

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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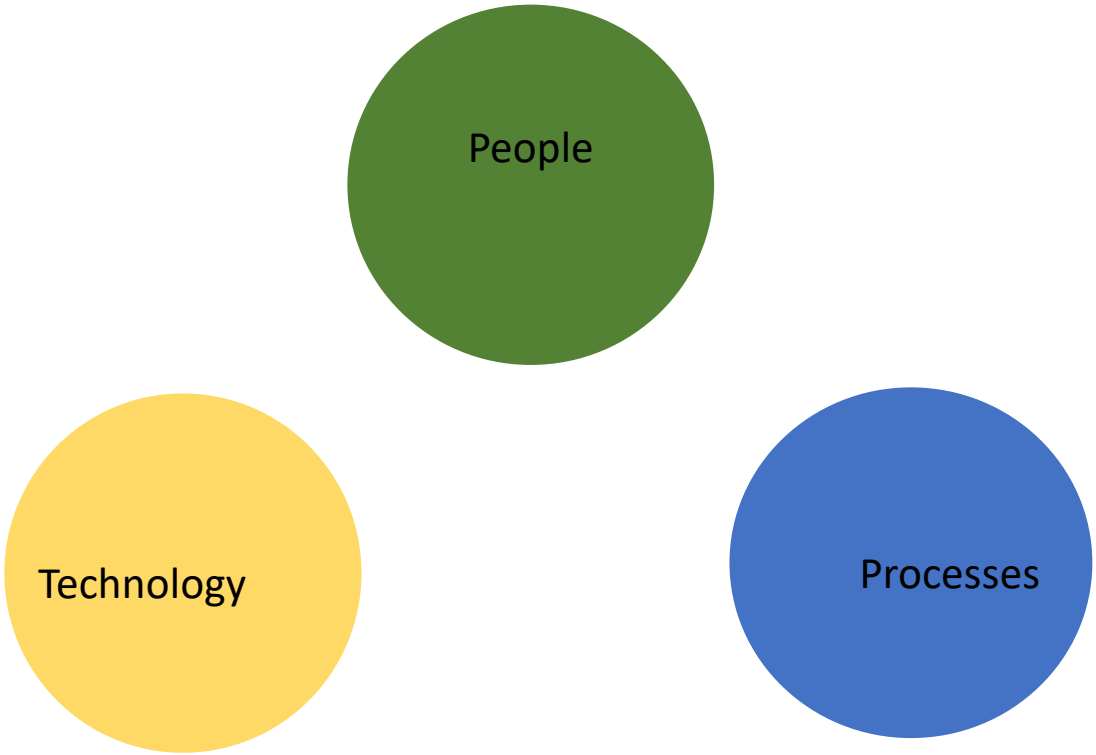
Silos: An Impediment to System Building



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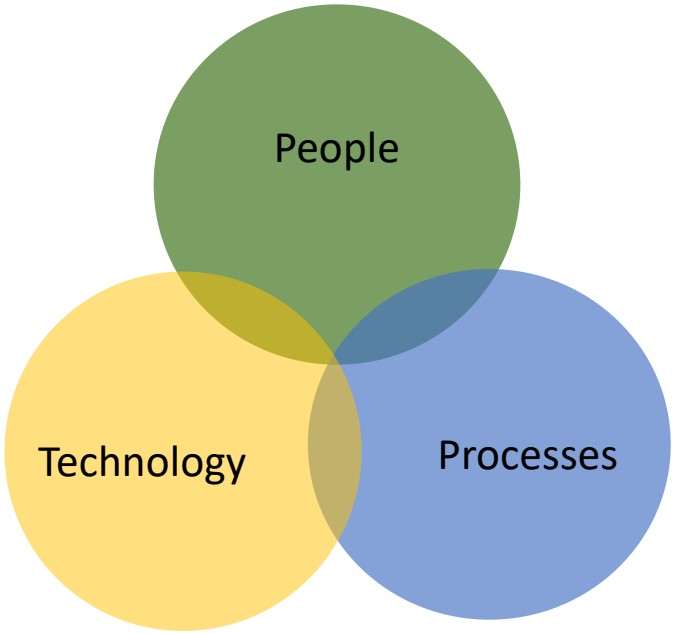
The Power of Integration: Connectivity and Interoperability



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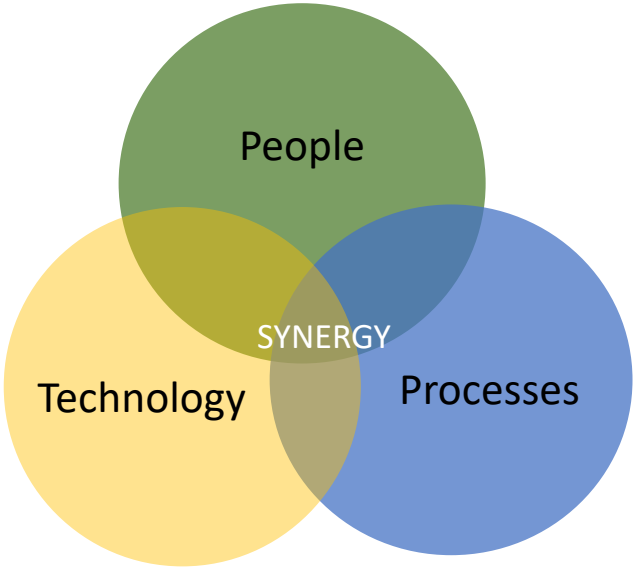
The Power of Integration: Creating Synergy



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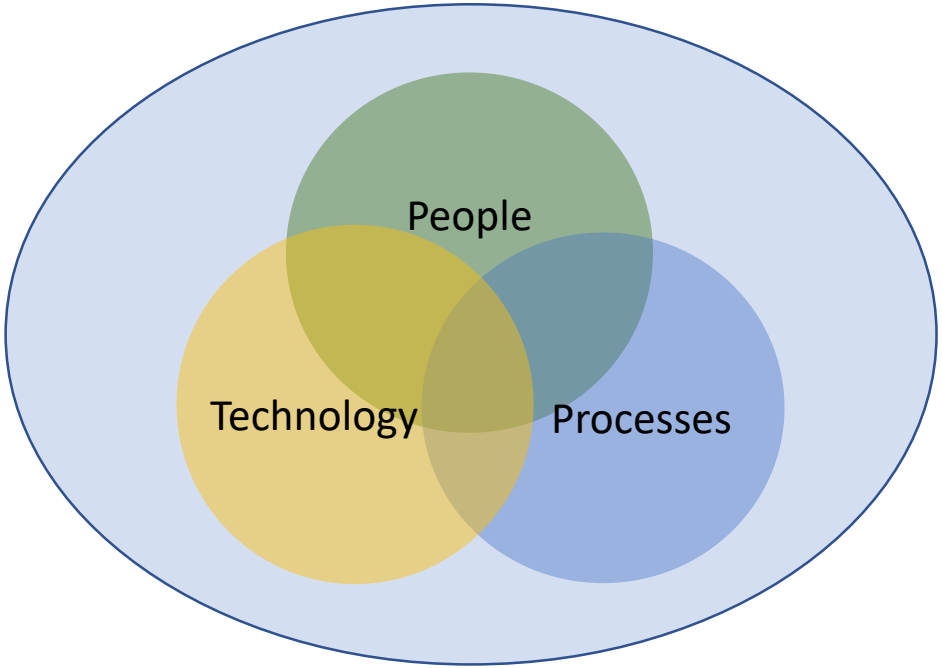
Integrated Systems: Realizing the Synergy of the Whole



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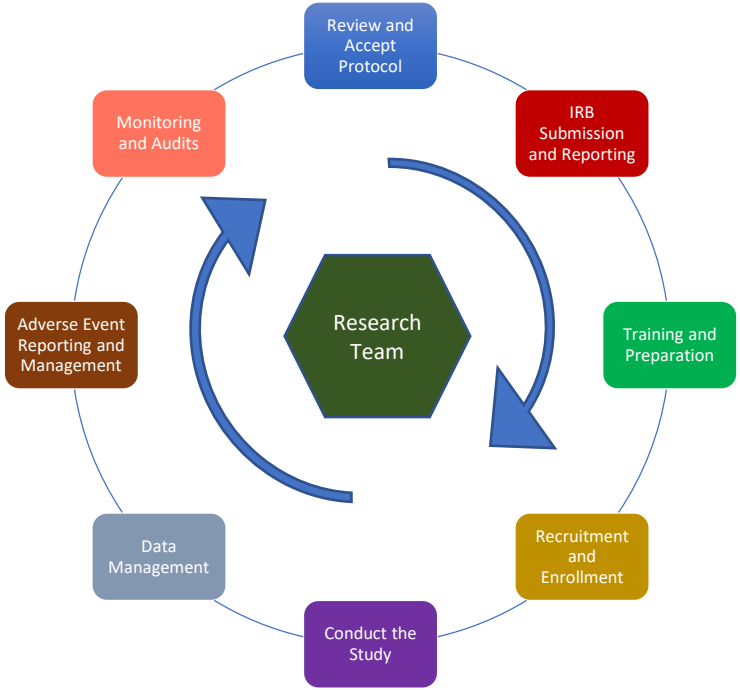
A World View of the Clinical Trials Process from the Perspective of a Research Site

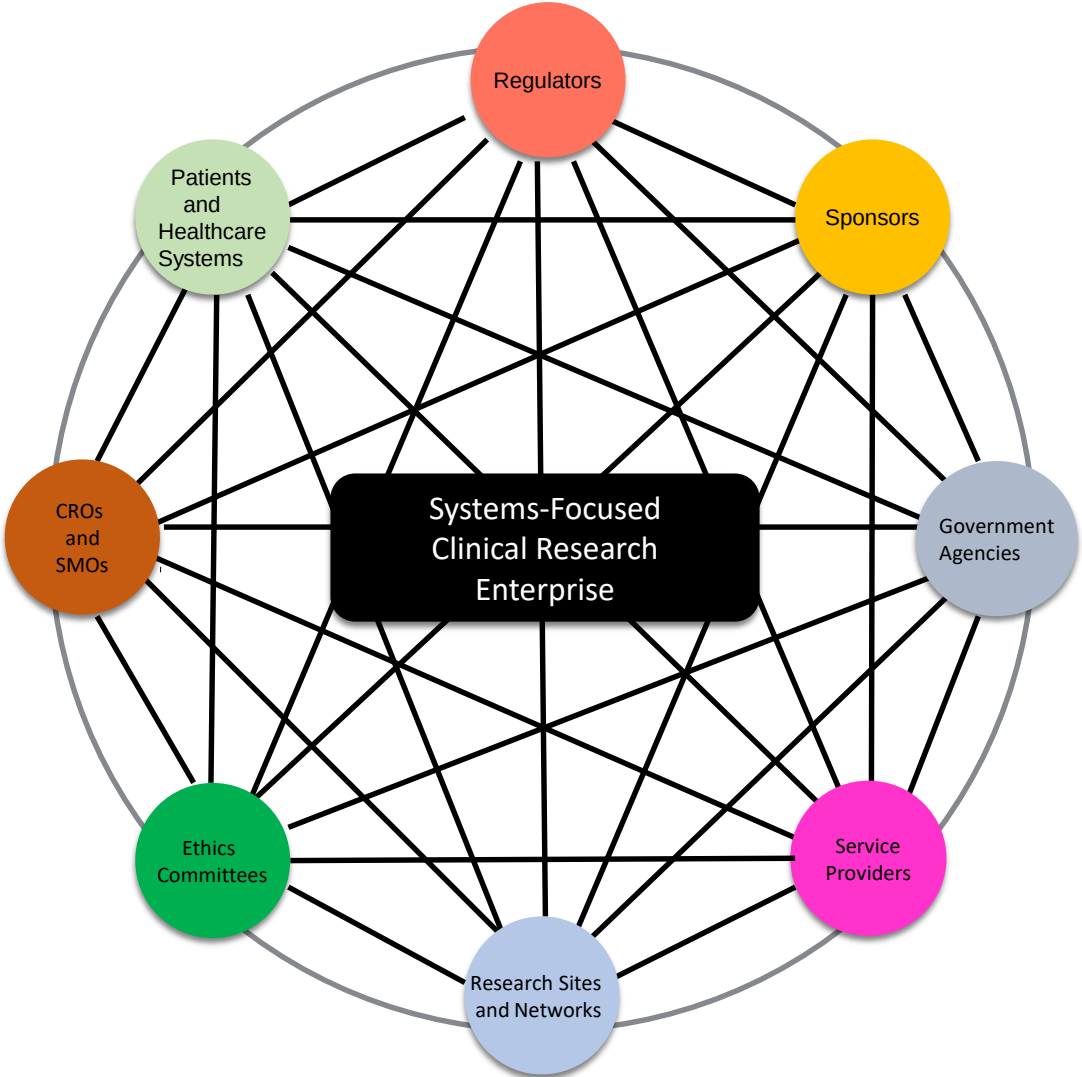


Inputs

Test Articles
Protocols
Contracts
Regulations
Boundaries
Logistics
Finances
Technologies
Collaborations
Patents

People

R&D Team
Operations Team
Investigators
Coordinators
Monitors
Auditors
Technologists
Data Managers
Ethicists
Regulators
Patients/Families
Physicians
Administrators



Processes

Development
Pre-Clinical
Protocol Development
Regulatory Approval
EC Approval
Site Selection
Study Start-up
Trial Conduct
Data Collection
Data Analysis
Quality Management
Adverse Events
Reporting
Monitoring
Auditing
NDA
Approval
Marketing
Advertising
Manufacturing
Distribution

Outcomes

Data
Safety
Quality
Efficiency
Approval
Market Share
Profitability
Sustainability
Respectability
Better Health
Quality of Life
Productivity
Development

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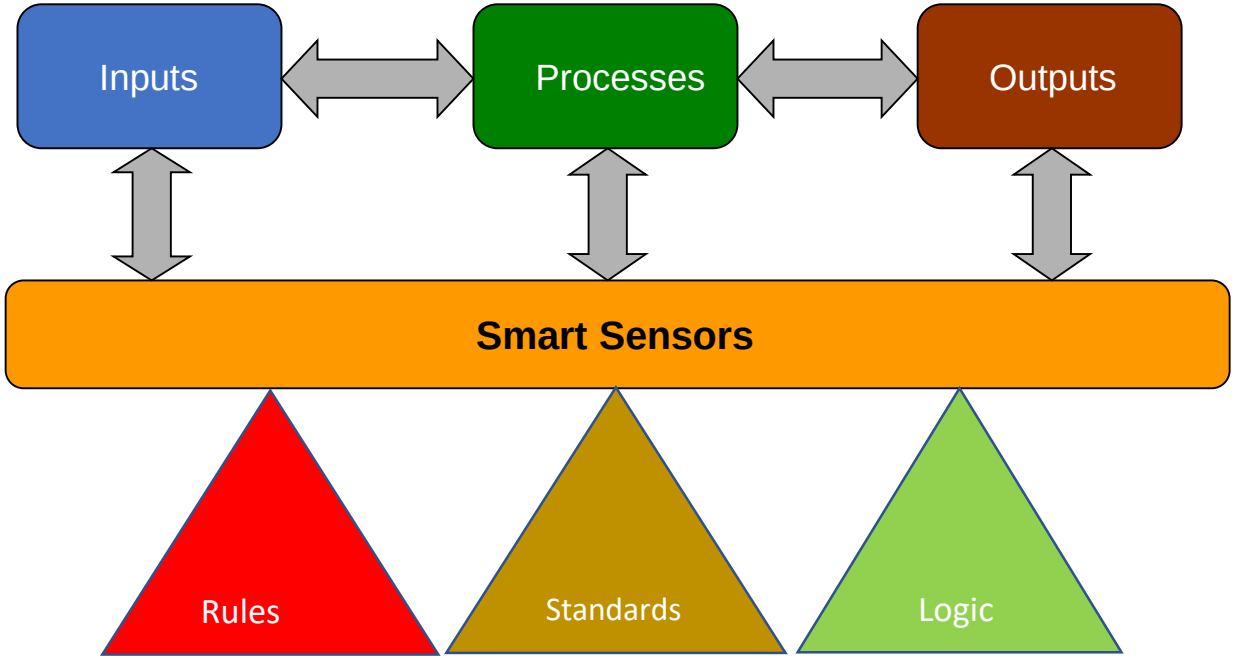
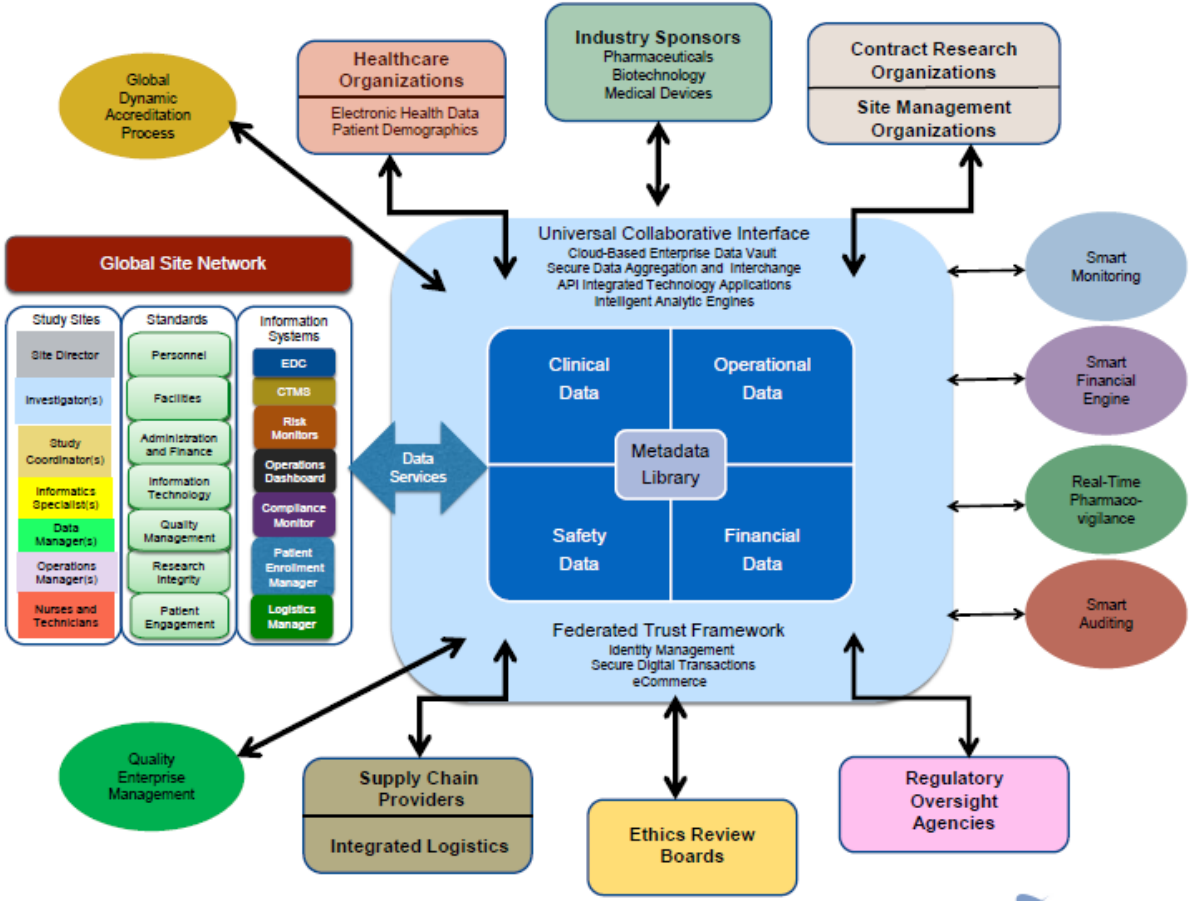
Smart Systems for Performance Enhancement and Quality Management



ACRES System Overview



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ACRES

Alliance for Clinical Research Excellence and Safety

--building a global collaborative system for clinical research excellence, together!

http://www.acresglobal.net

The Global Language of Business

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***

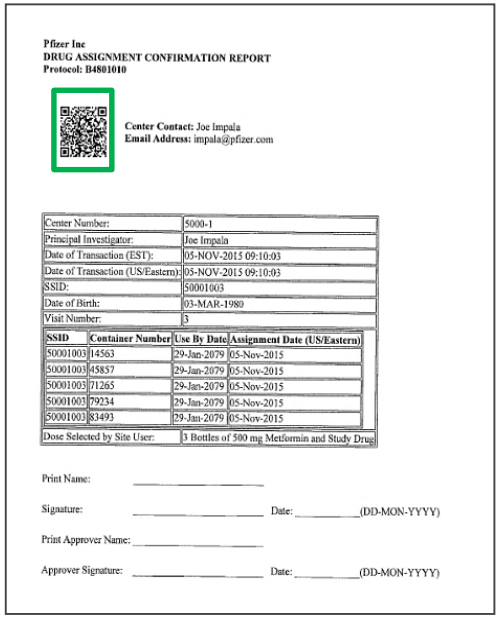
Originally launched in 2013 as POC

Version 2.0.0 is available now for ***US market only***

Download on the App Store

GET IT ON Google Play

Kit Verify App



Pfizer Inc
DRUG ASSIGNMENT CONFIRMATION REPORT
Protocol: B4801010

Center Contact: Joe Impala
Email Address: impala@pfizer.com

Center Number:	5000-1
Principal Investigator:	Joe Impala
Date of Transaction (EST):	05-NOV-2015 09:10:03
Date of Transaction (US/Eastern):	05-NOV-2015 09:10:03
SSID:	50001003
Date of Birth:	03-MAR-1980
Visit Number:	3

SSID	Container Number	Use By Date	Assigament Date (US/Eastern)
50001003	14563	29-Jan-2079	05-Nov-2015
50001003	45857	29-Jan-2079	05-Nov-2015
50001003	71265	29-Jan-2079	05-Nov-2015
50001003	79234	29-Jan-2079	05-Nov-2015
50001003	83493	29-Jan-2079	05-Nov-2015

Dose Selected by Site User:	3 Bottles of 500 mg Metformin and Study Drug

Print Name: _____

Signature: _____ Date: _____(DD-MON-YYYY)

Print Approver Name: _____

Approver Signature: _____ Date: _____(DD-MON-YYYY)

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 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

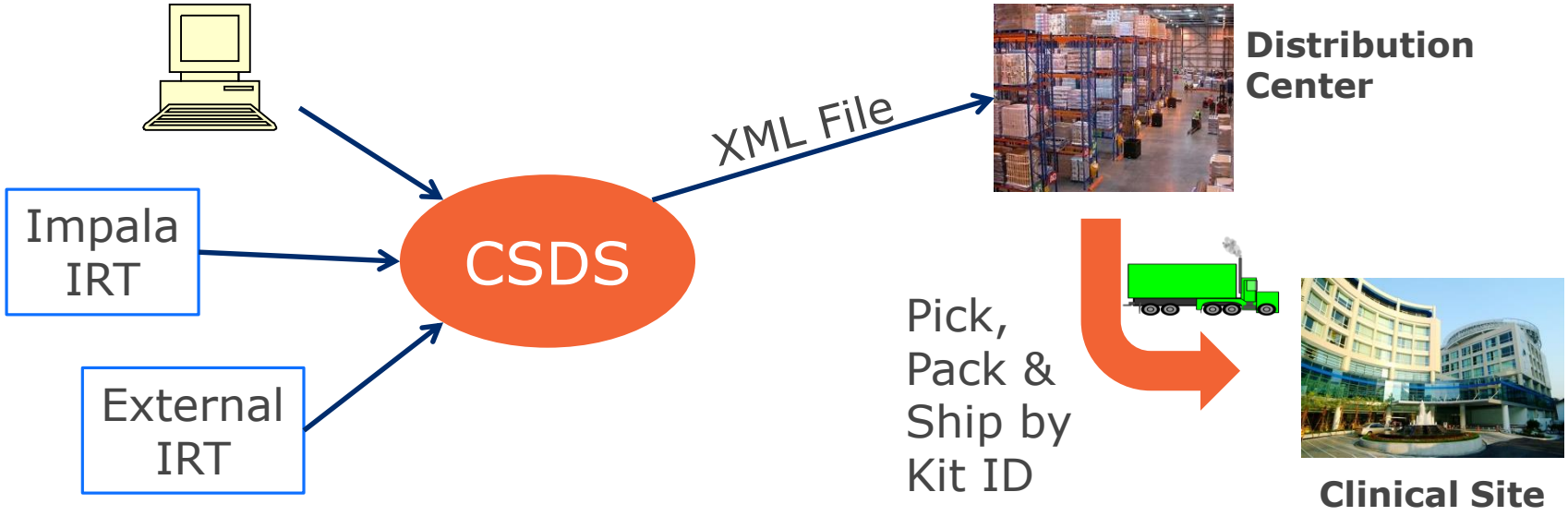
- WIP has a barcode on the label with kit ID only.
- Internal inventory system uses the barcode to advance WIP from one operation to the next.
- If system scanners see anything other than a valid kit ID, wrong part number designation is thrown.

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.

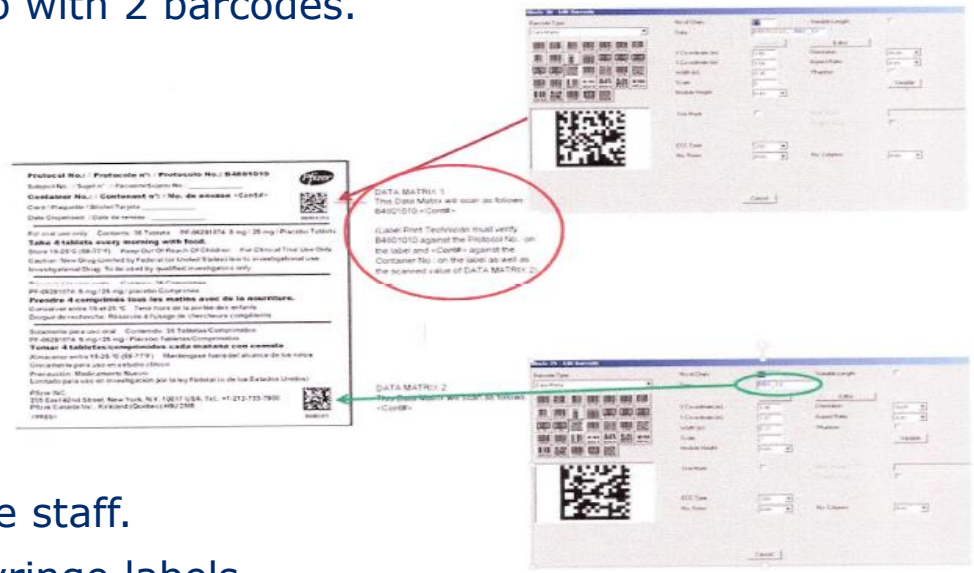
Distribution System Challenges

Clinical Supply Distribution System (CSDS)



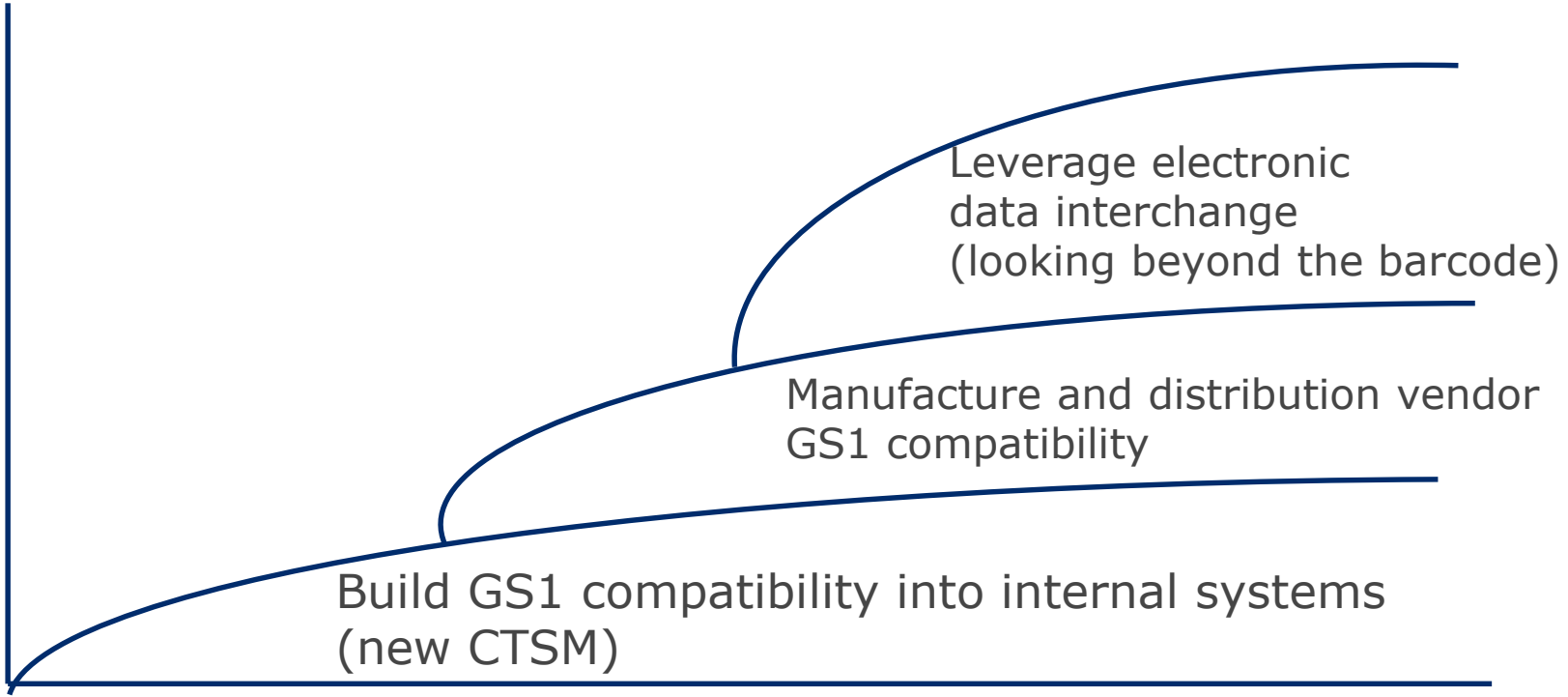
Interim Solution

No choice but to go with 2 barcodes.



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

Three Horizon Vision



Thank you
Contact Information

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Clinical Supply Chain Strategy and Management

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E hans.o.vonsteiger@pfizer.com

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

DANA-FARBER
CANCER INSTITUTE

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.

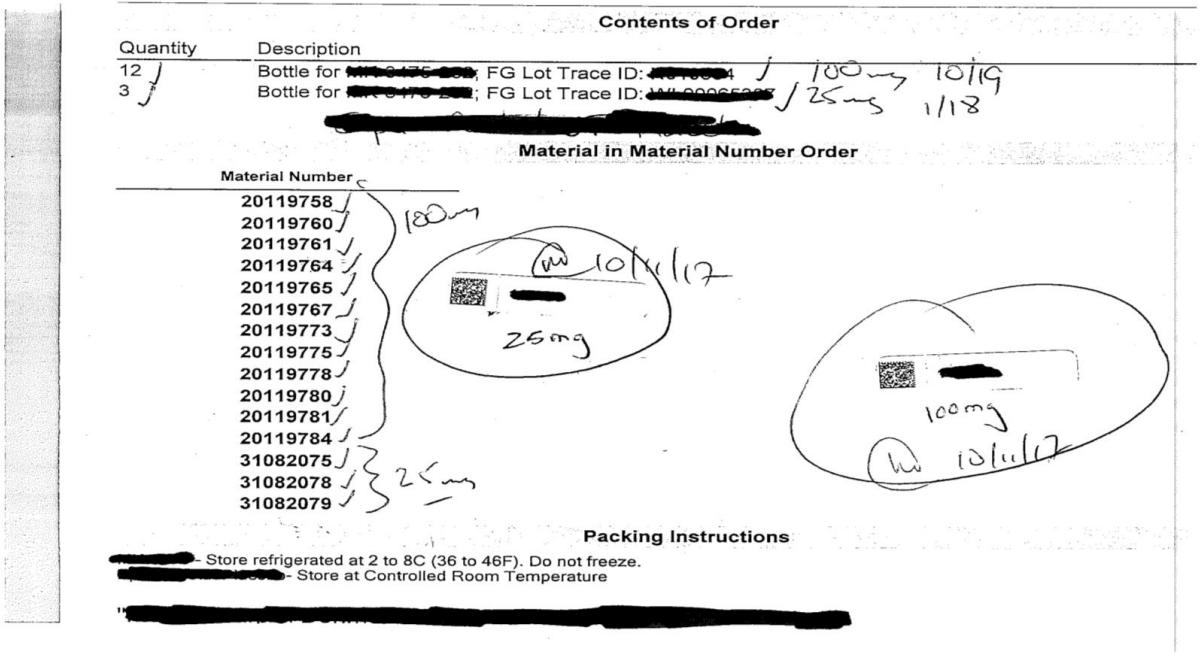
DFCI IDS-2-D Data Matrix Barcode

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

Quantity	Description
12	Bottle for [redacted]; FG Lot Trace ID: [redacted] 100mg 10/19
3	Bottle for [redacted]; FG Lot Trace ID: [redacted] 25mg 1/18

[redacted]

Material in Material Number Order

Material Number
20119758
20119760
20119761
20119764
20119765
20119767
20119773
20119775
20119778
20119780
20119781
20119784
31082075
31082078
31082079

100mg

[redacted] 10/11/17

25mg

100mg

[redacted] 10/11/17

25mg

Packing Instructions

[redacted] - Store refrigerated at 2 to 8C (36 to 46F). Do not freeze.

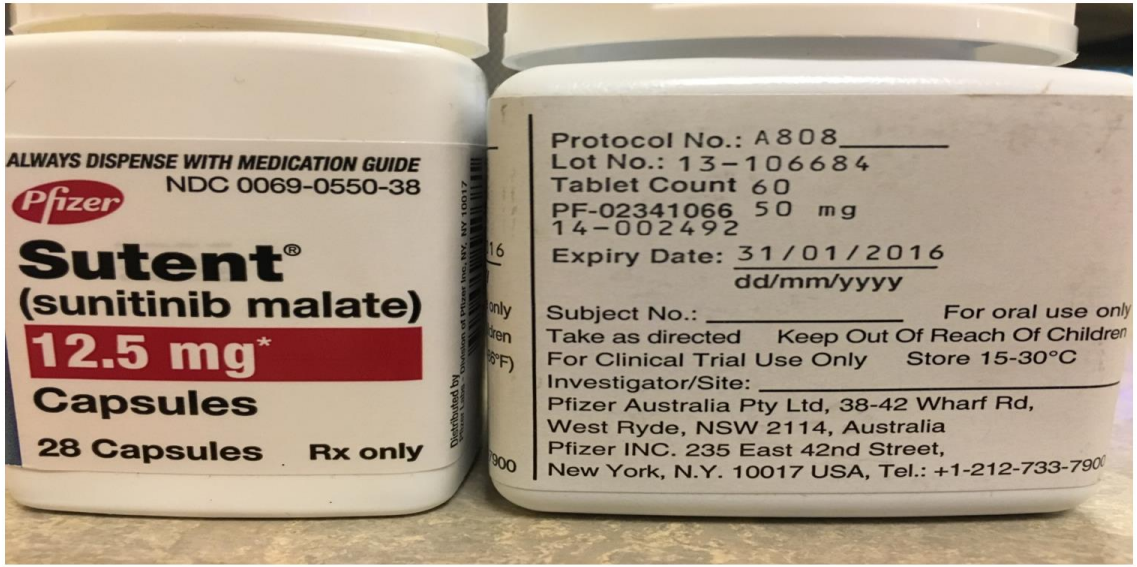
[redacted] - Store at Controlled Room Temperature

[redacted]

DANA-FARBER CANCER INSTITUTE

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

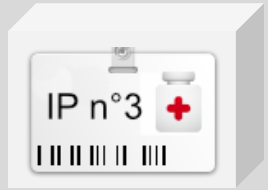
Sylvain Alberola, Head of Industrial Development, Clinical Supply Chain, Sanofi
Pierre Fernandez-Barbereau, Project Management, Clinical Supply Chain, Sanofi
October 18th 2017

What are we going to talk about ?

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

Clinical trials challenges

Clinical trials challenges
Specific context



Patient #12305

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

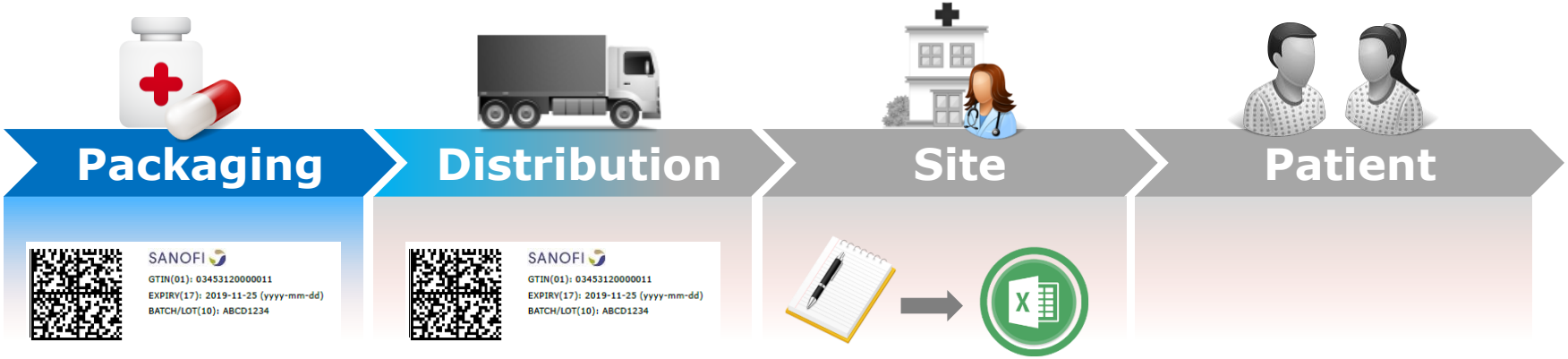
From production to patient (simplified view)

Packaging	Distribution	Site	Patient
Quality Controls (Printed label controls, synchronization, completion of batches)	***Shipments preparation*** (Warehouse and stock management)	***IRT interactions*** (Allocation, Return, Accountability, Reconciliation, Destruction)	***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



Sanofi: GS1 "like" datamatrix
Partners: Specific solutions

Handwriting, Excel,
IRT Web access

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)

	GS1 AI	What's in there	Example
Outer level (Kit Level)	**(01)** GTIN-14	**Prefix + Kit Type + Check digit**	**03607980000012**
	(240) Additional ID	**Study Number**	**EFV12345**
	(21) SN	**Treatment Number**	**T000093**
	(10) Batch/Lot	**Batch Number**	**00001**
	(17) Expiration date (YYMMDD)	**Expiration Date** (Not used today)	**181005**
Inner level (element in the Kit)	**(8006)** GCTIN, ID of the component of a trade item	**For each element in the kit Prefix + Kit Type + Check digit + Rank**	**03607980000012 0106 (syringe 1 of 6)**
	(21) SN	**Treatment Number**	**T000093**
	(17) Expiration date (YYMMDD)	**Expiration Date** (Not used today)	**181005**
	(240) Additional ID	**Study Number**	**EFV12345**

So, why we should have it ?
(yes, why ?)

Why we should have it
Benefits

Packaging

- Camera control automation
- Synchronization between levels of packaging
- Improve chain with partners
- Overall quality increase

Distribution

- Simplified common identification & tracking
- Depots automation
- Late stage customization easiness

Investigational site

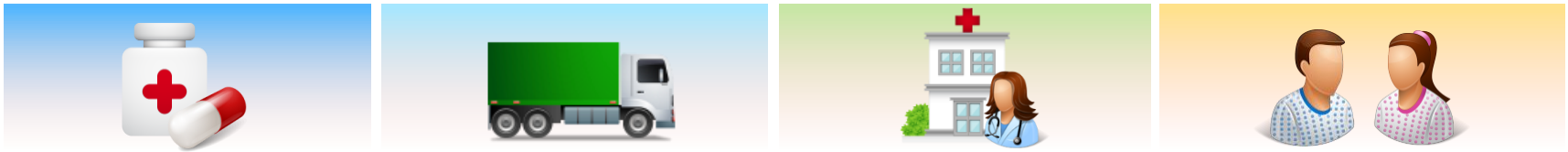
- A unique automated way to manage kits (~~hand writing~~)
- Overall risk and workload decrease
- Global traceability improvement

Patient

- Safety !
- Additional services (online information & help, community)
- Devices interactions

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
Contact Information

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Questions from the audience

Please remember…

GS1 US

The Global Language of Business

Laying the Foundation Today for Tomorrow's Innovations

Pharmaceutical leaders call for the use of GS1 Standards in clinical research

Executive Summary

Clinical trials are carefully designed studies to test the safety and efficacy of medicines in healthy volunteers and patients. At any one time, biopharmaceutical companies are sponsoring tens of thousands of ongoing clinical trials that are conducted with investigators, ranging from the largest research institutions to solitary practitioners.

With the mapping of the human genome and the advent of personalized medicine, clinical trials have become even more complex. Instead of seeking effective treatment for a thousand diseases, the clinical research community is seeking effective treatment for millions of unique patients. Thousands of investigational products—each identified and named in different ways by each pharmaceutical sponsor—are being investigated.

Research pharmacies like the one at the Dana-Farber Cancer Institute (Dana-Farber) face the challenge of managing hundreds of studies across multiple pharmaceutical sponsors, each with its own unique packaging and labeling.

Biopharmaceutical companies take many steps to ensure the safety and integrity of the clinical supply chain that provides investigational products to patients. Investigational products are typically serialized and barcoded; however, to-date there has not been a common method for barcoding among biopharmaceutical companies.

Amgen, Eli Lilly and Company (Eli Lilly), MSD and Pfizer have recognized the value of using standardized barcodes for investigational products. The use of standardized barcodes will help enable more efficient processes at larger institutions such as Dana-Farber that are already using an electronic inventory system with system-generated barcodes to manage investigational products. GS1 Standards will also provide the foundation for technology innovations that can benefit all investigators and ultimately patients.

Rather than create a new standard, Amgen, Eli Lilly, MSD and Pfizer are encouraging the adoption of GS1 Standards for the identification of investigational products and sharing information across the clinical research ecosystem. This will build upon the significant investments to implement GS1 Standards that are already being made across the pharmaceutical industry for approved drugs.

Rather than create a new standard, Amgen, Eli Lilly, MSD and Pfizer are encouraging the adoption of GS1 Standards for the identification of investigational products and sharing information across the clinical research ecosystem. This will build upon the significant investments to implement GS1 Standards that are already being made across the pharmaceutical industry for approved drugs.

- 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

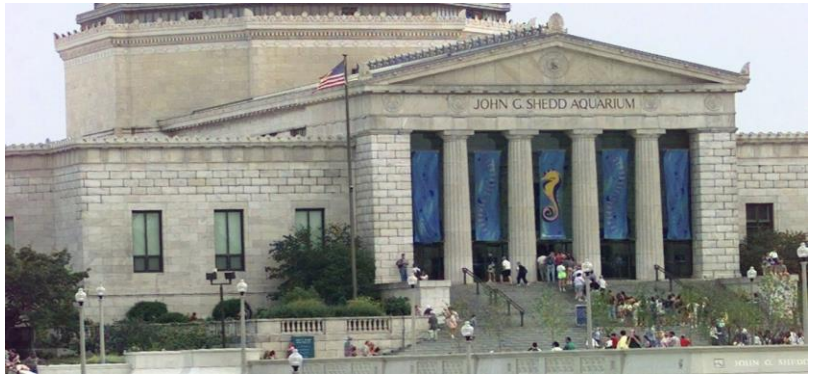
1200 S Lake Shore Dr.
Chicago, IL 60605

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!