THE ROLE OF STANDARDS IN CLINICAL TRIALS

GS1 Healthcare Conference

Mike Meakin, Vice President, Global Quality Regulatory & Compliance
Noordwijk-Amsterdam, the Netherlands

DHL Life Sciences & Healthcare

Today's speakers

Olivia Chauvel, Hospital Pharmacist, CH Victor Dupouy, France

Hans von Steiger, Directory / Team Leader Clinical Supply Chain Strategy Management, Pfizer, US

Pierre Fernandez-Barbereau, Project Management Clinical Supply Chain, Sanofi, France

Our agenda

- 5 min intro – Mike
- 15 min presentation – Olivia
- 15 min presentation – Hans
- 15 min presentation – Pierre
- 25 min Q & A from the audience – Facilitated by Mike
- 5 min close – Mike

For questions from the audience we will use Slido
You can post questions at any time throughout the session!

1. Go to **slido.com**
2. Enter **#GS1HCNoordwijk**
3. Select the **session you are in**
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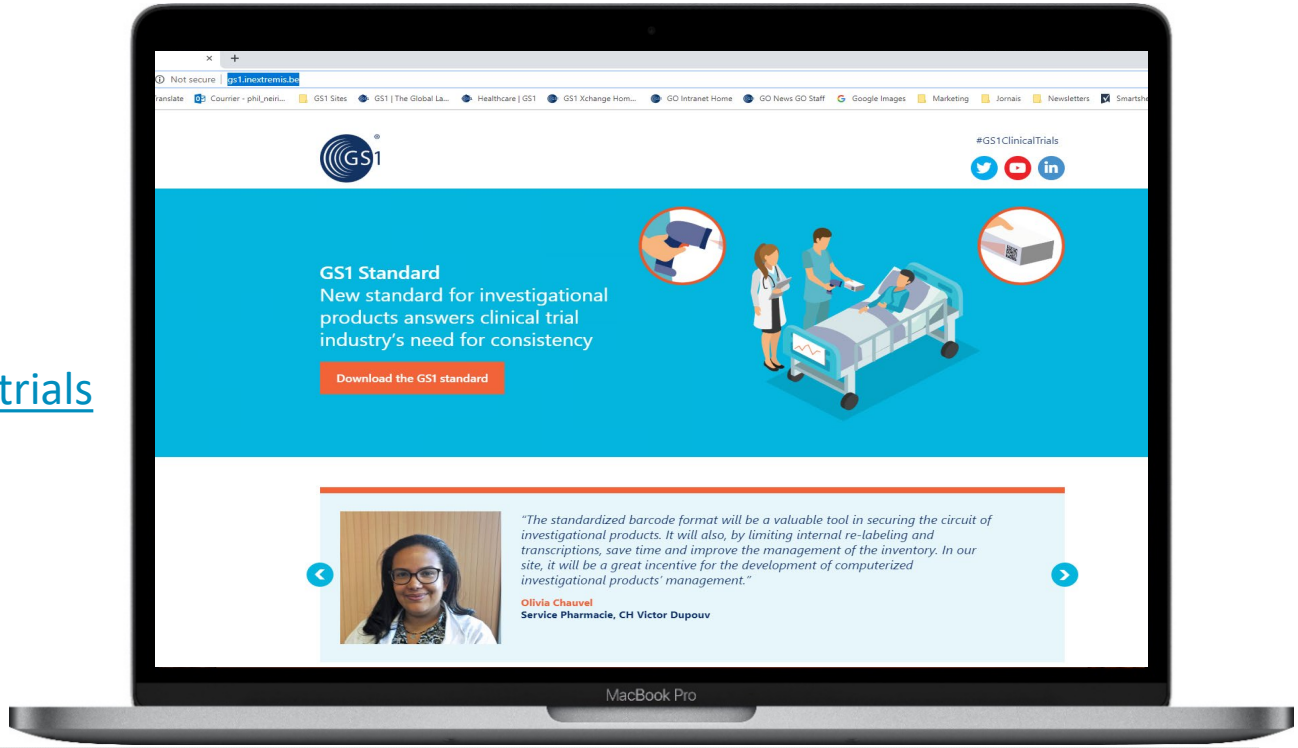
5. Make sure you **enter your full name** so that if the questions you’ve raised are not selected, the GS1 team can revert to you
6. **Post your questions!**

The GS1 application standard for Identification of Investigational Products in Clinical Trials is released!

[Go to: www.gs1.org/clinical-trials](www.gs1.org/clinical-trials)



The role of standards in Clinical Trials
Hospital perspective

Dr Olivia Chauvel
Pharmacist
Victor Dupouy Hospital (Argenteuil - France)

Centre Hospitalier
Victor Dupouy
Argenteuil

A few definitions

- **Clinical trial** → interventional study aiming to evaluate an intervention.
  - Interventions include drugs, medical devices, procedures, vaccines, …
- **Comparator** → An investigational or marketed active product, or placebo, which is used as a reference in a controlled clinical trial.
- **Placebo** → An item that looks identical to the evaluated intervention but contains no active ingredient
- **Auxiliary product** → A medicinal product used for the needs of a clinical trial as described in the protocol, but not as an investigational product.

A few definitions

- **Protocol ID** → The identifier, numeric or alphanumeric, assigned to a specific clinical study.
- **Ancillary item / supplies** → Additional supplies required for the study e.g. syringes, pumps, needles etc.
- **Interactive Response Technology (IRT)** → Umbrella term that refers to both Interactive Voice Response System (IVRS) and Interactive Web-based Response System (IWRS) – systems used for communication of information during a trial.

Stakeholders

- **Sponsor**
  - The organization or person who initiates the study and who has authority and control over the study.
  - Who ? National agencies, Industry, Others (including individuals, universities, and community-based organizations).
- **Investigator**
  - A researcher involved in a clinical study.
- **CRO** (Contract research organization)
  - A company that provides support to the industries in the form of research services outsourced on a contract basis.
- **Subjects** participating to a clinical trial
  - Rights protected by ICH-GCP guidelines

Clinical trials features

- **Monocenter trial** → only one site
- **Multicenter trial** →more than one site
  - Benefits : a larger number of participants, different geographic locations, the possibility of inclusion of a wider range of population groups, and the ability to compare results among centers, all of which increase the generalizability of the study.

- **Randomized allocation** → A type of allocation strategy in which participants are assigned to the arms of a clinical trial by chance

Clinical trials features

- **Masking/Blinding** is a clinical trial design strategy in which one or more parties involved in the trial, such as the investigator or participants, do not know which participants have been assigned which interventions.
  - **Open-label** → all the parties (including participants) know the attributed intervention
  - **Single-blind masking** → The investigator or the participant doesn't know which intervention was attributed
  - **Double-blind masking** → Both investigator and participant don't know which intervention was attributed

At the Clinical Site …

Accountability log recording the whole process

1 - IP reception on site

2 - Controlled-temperature storage

3 - IP allocation

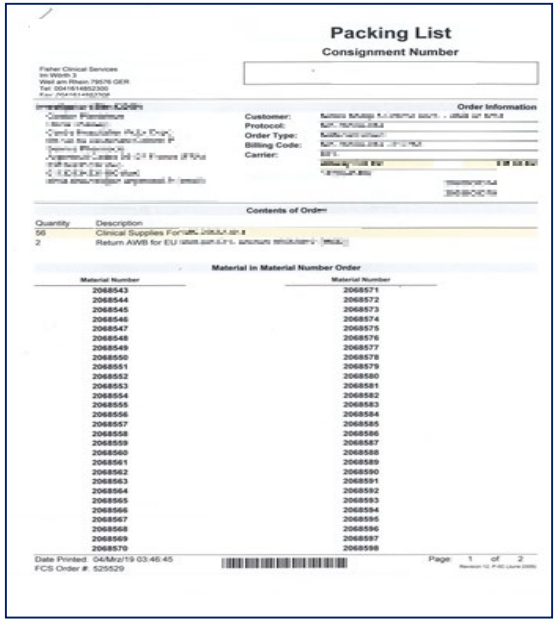
4 - IP dispensation to patient

5 - Used IP return to site

6 - IP return to sponsor / Disposal

Current « paper » IP management example

From the delivery form…



Packing List

Consignment Number

Order Information

Customer:
Protocol:
Order Type:
Billing Code:
Carrier:

Contents of Order

Quantity	Description
59	Clinical Supplies For
2	Return AWB for EU

Material in Material Number Order

Material Number	Material Number
2068543	2068571
2068544	2068572
2068545	2068573
2068546	2068574
2068547	2068575
2068548	2068576
2068549	2068577
2068550	2068578
2068551	2068579
2068552	2068580
2068553	2068581
2068554	2068582
2068555	2068583
2068556	2068584
2068557	2068585
2068558	2068586
2068559	2068587
2068560	2068588
2068561	2068589
2068562	2068590
2068563	2068591
2068564	2068592
2068565	2068593
2068566	2068594
2068567	2068595
2068568	2068596
2068569	2068597
2068570	2068598

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FCS Order #: 525529
Page 1 of 2

Current « paper » IP management example

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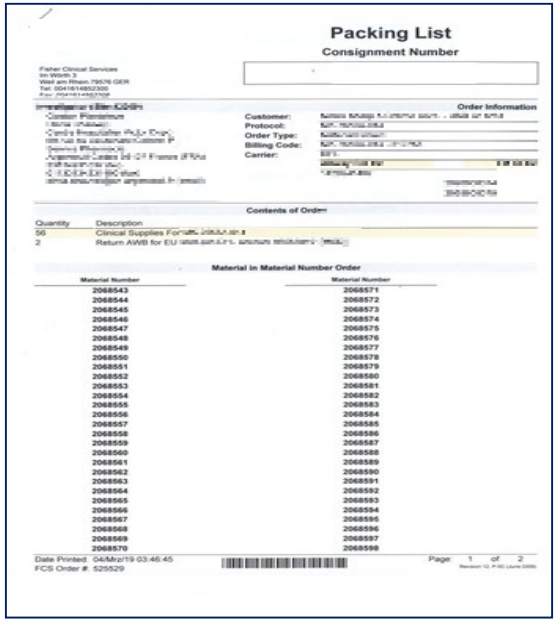

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2068551	2068579
2068552	2068580
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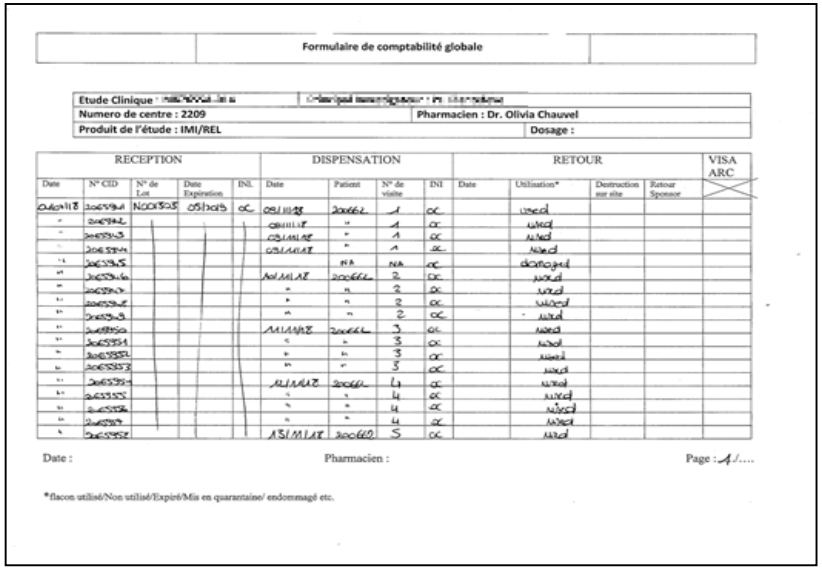


Formulaire de comptabilité globale

Etude Clinique :
Numero de centre : 2209 Pharmacien : Dr. Olivia Chauvel
Produit de l'étude : IMI/REL Dosage :

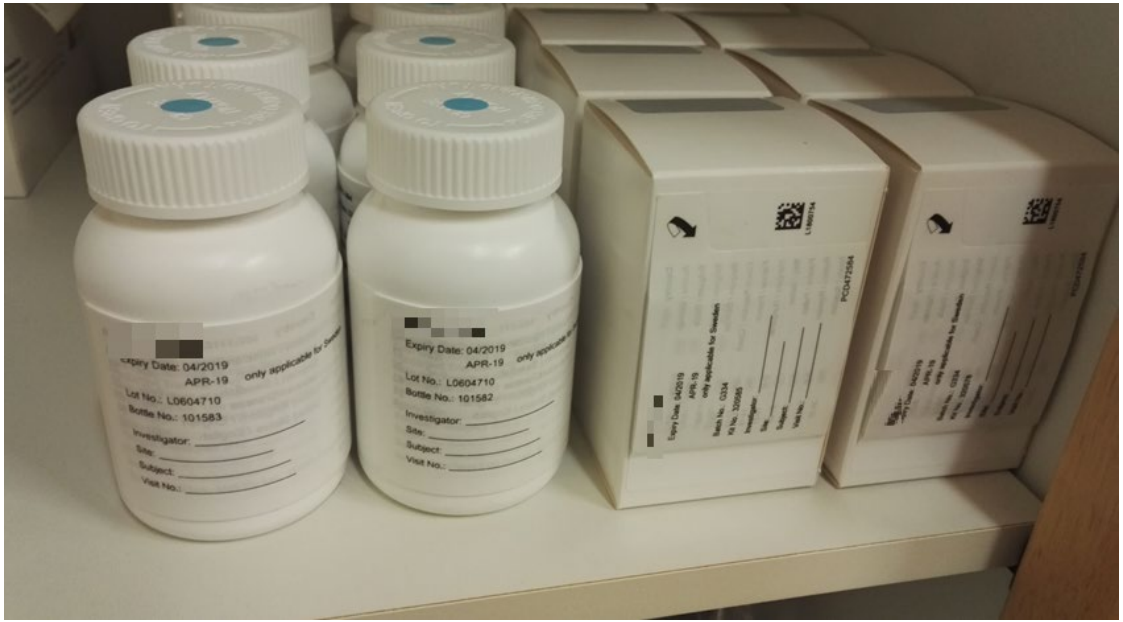
RECEPTION					DISPENSATION				RETOUR				VISA ARC
Date	N° CID	N° de Lot	Date Expiration	INI	Date	Patient	N° de visite	INI	Date	Utilisation*	Destruction sur site	Retour Sponsor	
04/04/18	2068564	N001505	05/2019	OC	05/11/18	200662	1	OC		used			
"	2068542				05/11/18	"	1	OC		used			
"	2068543				05/11/18	"	1	OC		used			
"	2068544				05/11/18	"	1	OC		used			
"	2068545					NA	NA	OC		damaged			
"	2068546				20/11/18	200662	2	OC		used			
"	2068547				"	"	2	OC		used			
"	2068548				"	"	2	OC		used			
"	2068549				"	"	2	OC		used			
"	2068550				21/11/18	200662	3	OC		used			
"	2068551				"	"	3	OC		used			
"	2068552				"	"	3	OC		used			
"	2068553				"	"	3	OC		used			
"	2068554				12/12/18	200662	4	OC		used			
"	2068555				"	"	4	OC		used			
"	2068556				"	"	4	OC		used			
"	2068557				"	"	4	OC		used			
"	2068558				15/01/19	200660	5	OC		used			

Date : Pharmacien : Page : 1/....

*flacon utilisé/Non utilisé/Expiré/Mis en quarantaine/ endommagé etc.

To the inventory log

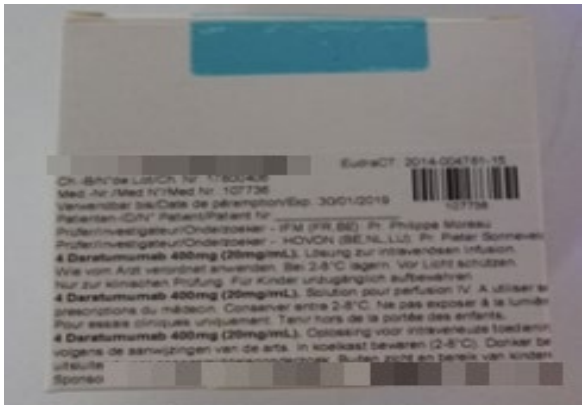
Numbered boxes and bottles

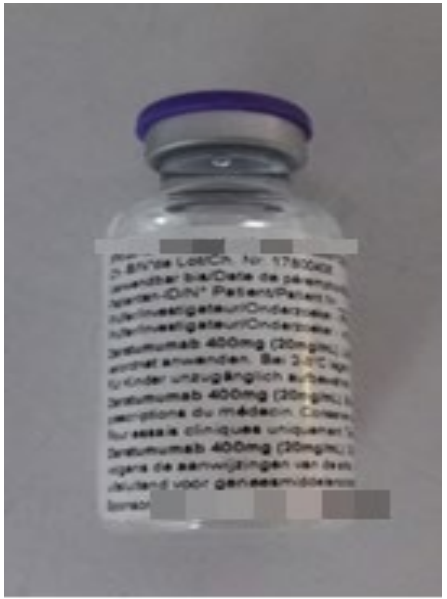


Numbered treatment kits (2 syringes)

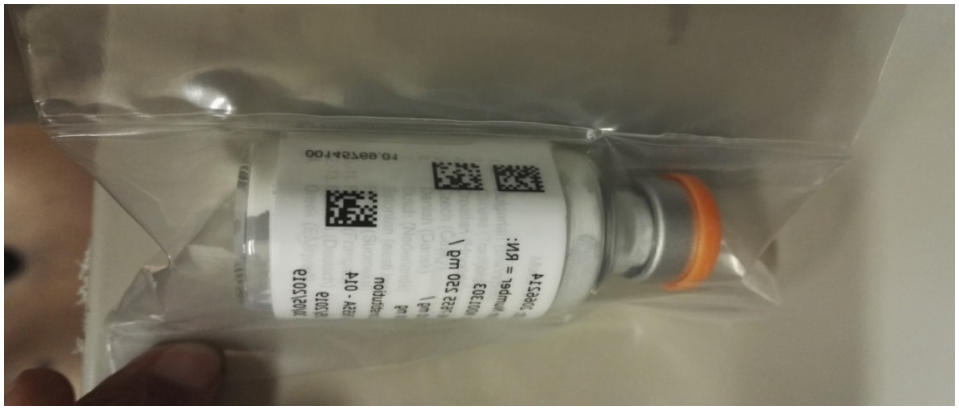
Numbered kit containing 2 dosages

Numbered box - containing 4 vials





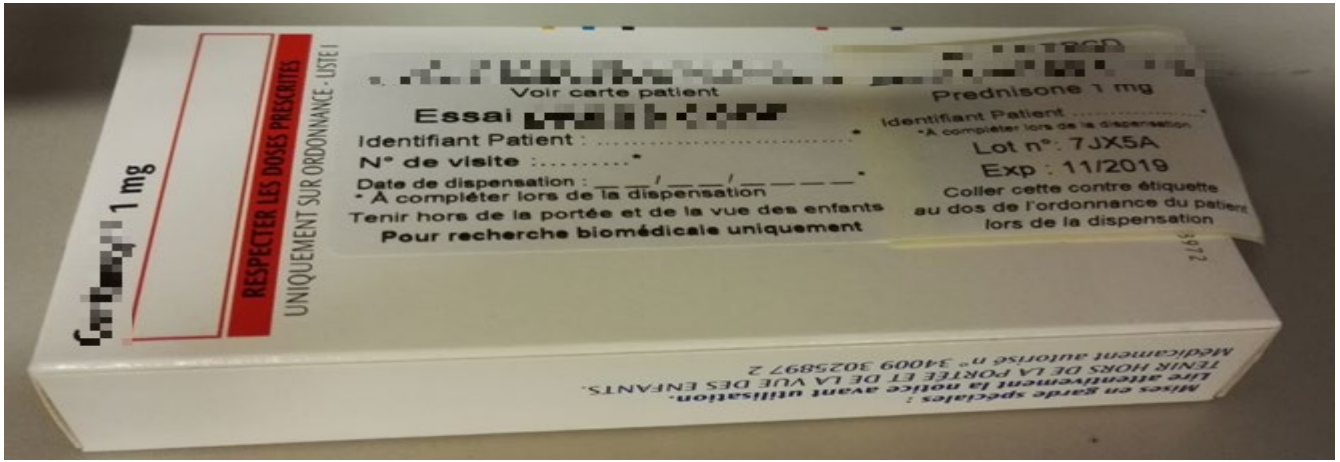
Vial labelling example



Numbered box

- No expiration date on the box → managed by IRT

Overlabelled commercial drugs



Benefits of IP labelling standardisation

- Saves time
- Improves inventory management
- Limits need for internal re-labelling and transcriptions
- Limits need to implement a different process for each trial
- Motivates to switch to an computerized organization
- Easy to adopt approaches that leverage the barcodes


Global

Clinical

Supply


GS1 Clinical Supply Standard

Healthcare Conference 2019

Hans von Steiger

Pfizer GLOBAL CLINICAL SUPPLY

Topics

- **Case study 1 – Pfizer Kit Verify**
- **Case study 2 – eLabels**
- **Summary**

GS1 CS Standards Team

Team Chairs

Olivia Chauvel; CH Victor Dupouy
Sylvain Alberola, Pierre Fernandez Barbereau; Sanofi
Hans von Steiger; Pfizer

Team Members

Pfizer Kit Verify App

Android & iOS dispensing verification mobile application for use with ***IRT***

<u>App Functionality</u>

1. Load patient kit dispensing list into the app memory
2. Physically pull kits to be dispensed from inventory
3. Scan each kit's barcode with the phone to confirm that the correct kit was selected

Pfizer Kit Verify App

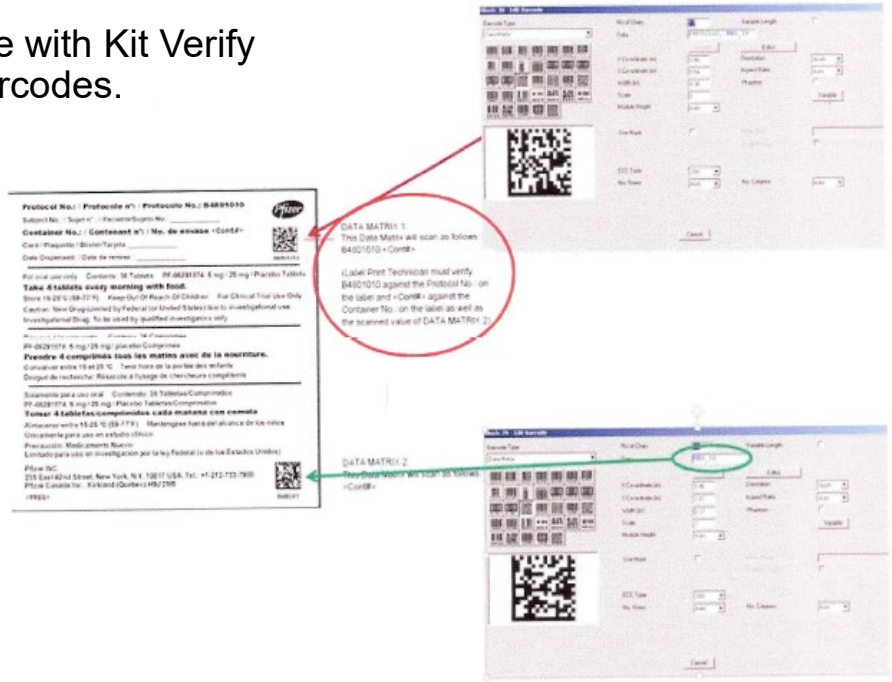
Pfizer Kit verify app barcode content

- 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

Pfizer Kit Verify App

Labeller barcode incompatible with Kit Verify
No choice but to go with 2 barcodes.



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

Clinical Supply eLabels

TransCelerate - a global biopharmaceutical research and development community collaboration to optimize development processes

- TransCelerate is coordinating an effort to enable eLabeling
- Reduce the amount of human readable text
- Make text available in a more user friendly electronic form
- The effort includes
  - Lobbying regulators
  - Encouraging pharma to pilot eLabels
  - Recommending eLabel design

Clinical Supply eLabels

Current State → **Potential Future State**

Booklet Label

Universal Label

Language neutral content on physical label to identify material

Study-specific eLabel

Full regulatory-compliant label on electronic device

* Detailed data may be added: e.g. SubjectID, investigator name

Summary

- Greater use of mobile devices as scanners shines light on problems with proprietary barcode content
- Clinical supply barcodes are not compatible across industry and vendor systems
- Mobile tools can’t be used across clinical supply pharma
  - eLabel readers are sponsor specific
  - IRT mobile interfaces need to be reprogrammed for each sponsor

Contact Information

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Industrial Development

Sanofi R&D
Clinical Supply Chain

From specific approaches to global standards

SANOFI

Clinical Supply Chain - Mission

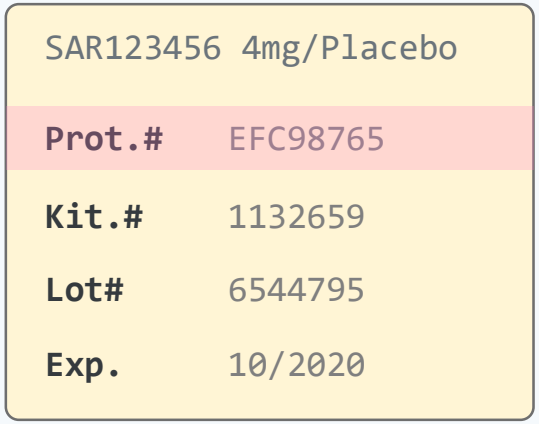
Ensure **alignment between clinical demand** and **pharmaceutical production master plans** of the various plants of the group

Operate the **customization of treatment packaging** by assembling different doses and products in support of clinical protocols for products in development

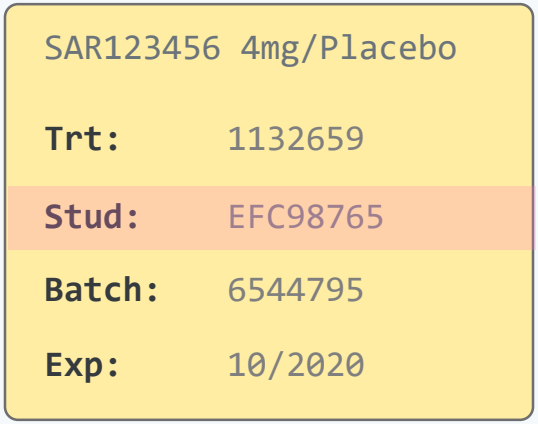
Package and distribute throughout the world by ensuring **traceability from production activities to each patient**

The kit identification

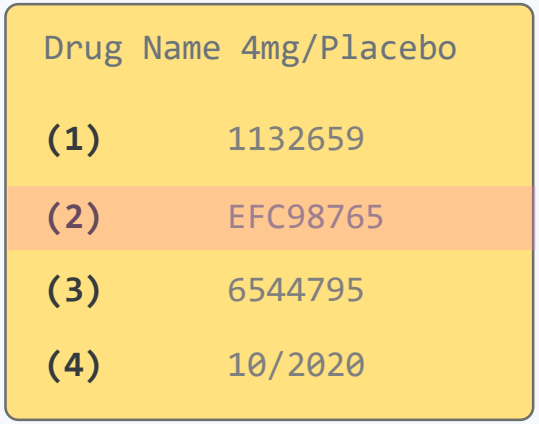
Deciphering the labels



Sponsor A



Sponsor B



Sponsor C

The kit identification
Using Barcodes

SAR123456 4mg/Placebo

(1) 1132659

(2) EFC98765

(3) 6547896

(4) 10/2020

(01)321654(240)1132659

EFC98765

6547896

The kit identification

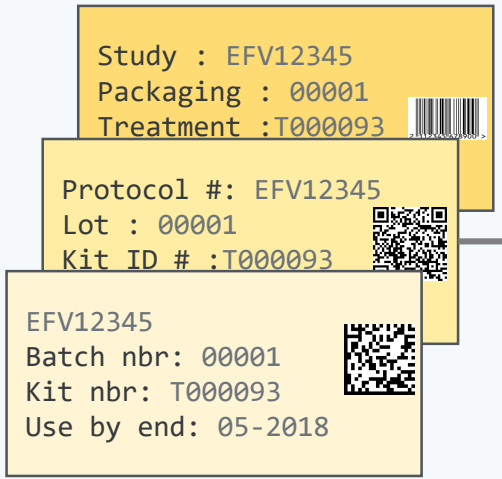
Extreme complexity for the site and along the supply chain

Most of it done by hand

As many adresses/url, credentials (login/password) and **processes** as sponsors, systems and or trials….

The kit identification

Need for **one** Global Interoperable Standard



SANOFI

The kit identification

GS1 standard for clinical trials

Unique, common & standard

Readable by everyone

First step, long journey

SANOFI

A global standard by the industry…

resulting from an industry-led working group

60
Representatives

37
Clinical trials Organisations

9
GS1 Global Representatives

Chaired by
CH Victor Dupouy, Pfizer
Sanofi

Pharmaceutical companies, hospitals, IT solution providers, contract research organisations

Source GS1 Healthcare

... for the industry

taking into account needs, constraints

Applicable to **blinded and unblinded trials**

Global Trade Item Number (GTIN) for unambiguous identification of investigational products and their components

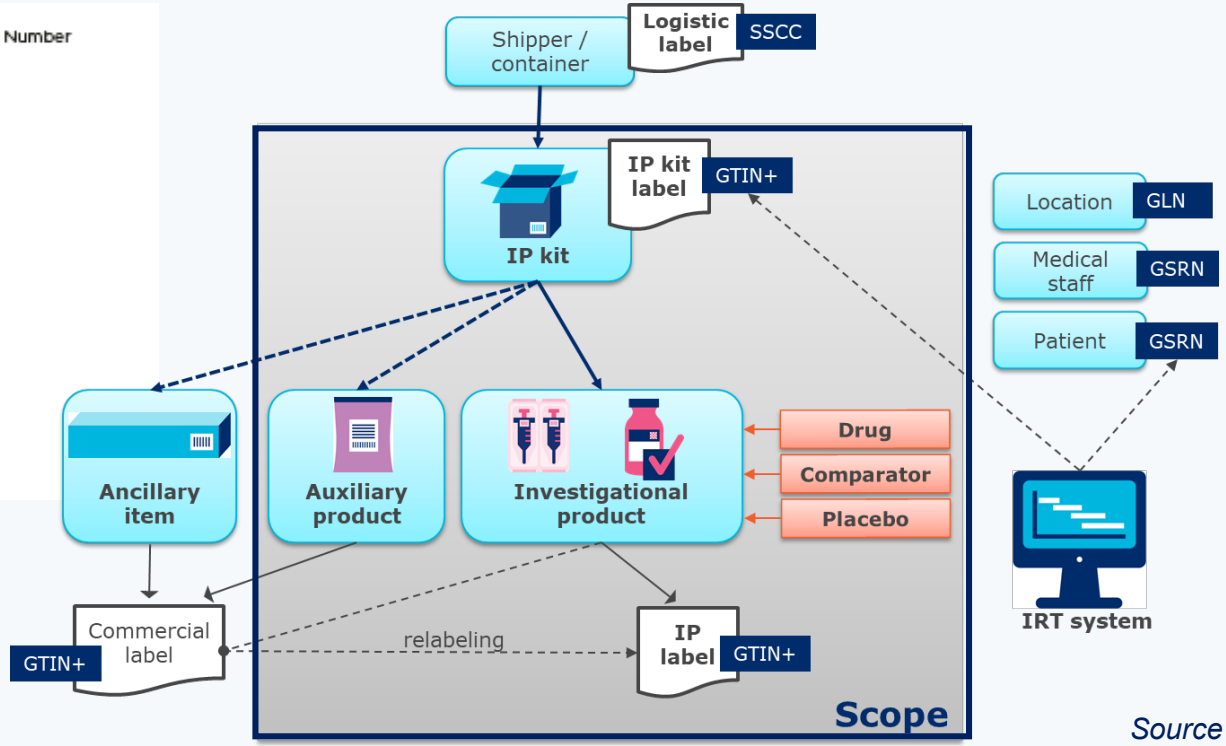
No requirement to include **expiration date within barcodes**

Respects space constraints of **labelling small kit components**

Source GS1 Healthcare

Kit identification

GS1 standard for clinical trials



Source GS1 Healthcare

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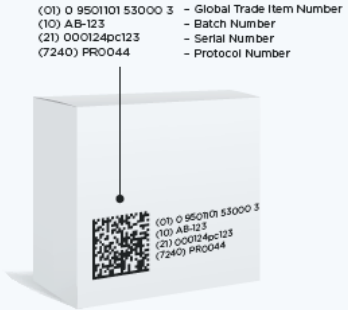
Across-the-board benefits

Benefits for suppliers

- Data compiled quicker
- Full supply chain traceability enabled
- Fewer transcription errors on the backend
- Less time spent verifying and validating data

Benefits for clinical trial sites

- Saves time
- Improves inventory management
- Limits need for internal re-labelling and transcriptions
- Easy to adopt approaches that leverage the barcodes



Benefits for patients

Most importantly, adopting the GS1 Standard adds an element of trust at all levels of the supply chain – a trust that ultimately extends to the patients themselves.

Source GS1 Healthcare

What’s next ?

Benefits and Challenges along the Supply Chain

Label & Pack Design

Standardization of Clinical Labels and information

Packaging Operations

- Ease In line Controls,
- Identification of kits / batches

Distribution

- Shipments preparation are more reliable
- Supply Chain stakeholders are sharing and exchanging information

Hospital

Ease Study Management activities at site level

Patient

- Connectivity to Patient's ecosystem (smartphones, diaries…)
- Innovative Solutions (eLabeling…)

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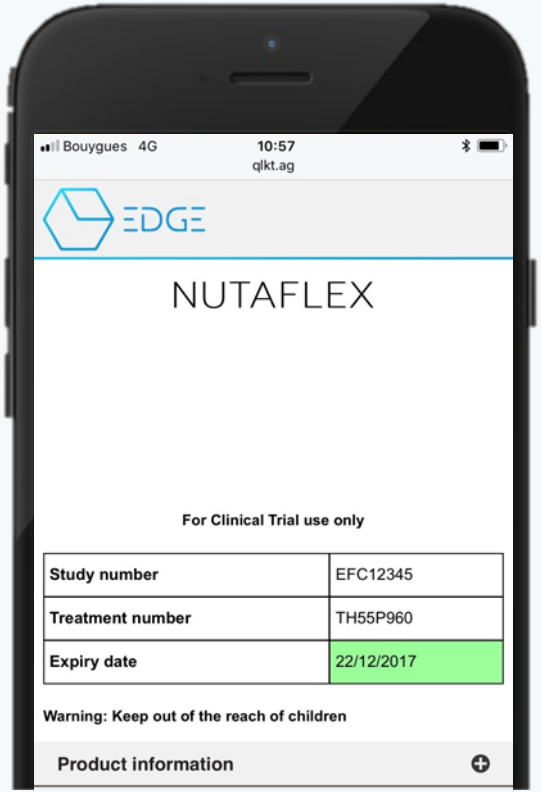
eLabeling

Product Information through GS1 Digital Link



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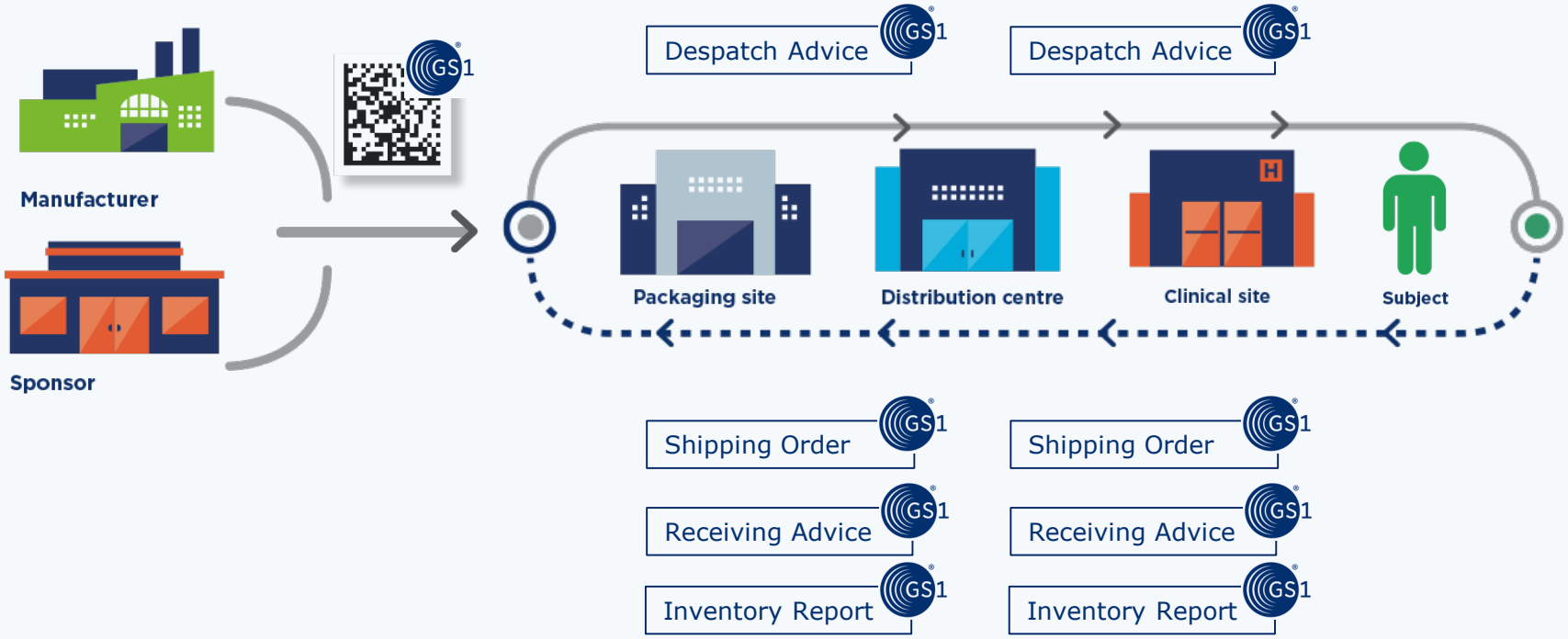
Standardized Supply Chain Transactions

Leveraging GS1 Healthcare EDI



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www.sanofi.com

THANK YOU!

#GS1ClinicalTrials www.gs1.org/healthcare

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Make the most of the conference!

And download the application standard for identification and barcoding of investigational products!

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