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
4. Go to “Questions”
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
The role of standards in Clinical Trials
Hospital perspective

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

- **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 ...

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

Accountability log recording the whole process
Current « paper » IP management example

From the delivery form...
Current « paper » IP management example

From the delivery form...

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
• No expiration date on the box $\rightarrow$ 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
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

App Functionality
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 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
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).
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

Booklet Label

Potential Future State

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
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From specific approaches to global standards
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

<table>
<thead>
<tr>
<th>Sponsor A</th>
<th>Sponsor B</th>
<th>Sponsor C</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAR123456 4mg/Placebo</td>
<td>SAR123456 4mg/Placebo</td>
<td>Drug Name 4mg/Placebo</td>
</tr>
<tr>
<td>Prot.#</td>
<td>EFC98765</td>
<td>(1) 1132659</td>
</tr>
<tr>
<td>Kit.#</td>
<td>1132659</td>
<td>(2) EFC98765</td>
</tr>
<tr>
<td>Lot#</td>
<td>6544795</td>
<td>(3) 6544795</td>
</tr>
<tr>
<td>Exp.</td>
<td>10/2020</td>
<td>(4) 10/2020</td>
</tr>
</tbody>
</table>
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 addresses/url, credentials (login/password) and processes as sponsors, systems and or trials…. 
The kit identification

Need for **one** Global Interoperable Standard

- Study: EFV12345
  - Packaging: 00001
  - Treatment: T000093

- Protocol #: EFV12345
  - Lot: 00001
  - Kit ID #: T000093

- Protocol: EFV12345
  - Batch nbr: 00001
  - Kit nbr: T000093
  - Use by end: 05-2018

- (01) ID
- (10) 00001
- (17*) 05/2018
- (21) T000093
- (7240) EFV12345

Industry Standard

- Fiability in process
- Quality of Data and Interfaces
- New Information and Services
The kit identification
GS1 standard for clinical trials

Unique, common & standard
Readable by everyone
First step, long journey
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

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
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 relabelling 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
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...)

Sub-Contractors
- Pharma B
- Pharma C

Packaging Operations
- Connectivity to Patient's ecosystem (smartphones, diaries...)
- Innovative Solutions (eLabeling...)

Sub-Contractors
eLabeling
Product Information through GS1 Digital Link

GS1 Digital Link

NUTAFLEX

For Clinical Trial use only

Study number: EFC12345
Treatment number: TH55P960
Expiry date: 22/12/2017

Warning: Keep out of the reach of children

Product information
Standardized Supply Chain Transactions
Leveraging GS1 Healthcare EDI
Contacts

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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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