GS 1 & eLabels

BREAKOUT SESSION

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more products. better treatments. reliably supplied.™
What is GS 1?

GS 1 is a not-for-profit organisation that develops and maintains global standards for business communications, the best known of these being the barcode
# GS 1 Barcodes

## The GS1 Barcodes

<table>
<thead>
<tr>
<th>GS1 EAN/UPC Family</th>
<th>GS1 2D Barcodes</th>
<th>GS1 QR Code</th>
</tr>
</thead>
<tbody>
<tr>
<td>UPC-A</td>
<td>GS1 DataMatrix</td>
<td>(01) 0 9501101 53000 3</td>
</tr>
<tr>
<td>EAN-13</td>
<td>(17) 150119</td>
<td>(10) AB-123</td>
</tr>
<tr>
<td>UPC-E</td>
<td>(01) 0 9501101 53000 3</td>
<td>(8200) <a href="http://example.com">http://example.com</a></td>
</tr>
<tr>
<td>EAN-8</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## GS1 DataBar Family

<table>
<thead>
<tr>
<th>Omnidirectional</th>
<th>Expanded</th>
<th>Stacked</th>
<th>Expanded Stacked</th>
</tr>
</thead>
<tbody>
<tr>
<td>(01) 0 9501101 53000 3</td>
<td>(01) 0 9501101 53000 3 (17) 140704</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Truncated</td>
<td>Limited</td>
<td>Stacked</td>
<td>(01) 0 9501101 53000 3 (3103) 000480</td>
</tr>
<tr>
<td>(01) 0 9501101 53000 3</td>
<td>(01) 0 9501101 53000 3</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

## GS1 1D Symbols used in General Distribution and Logistics but not at retail POS

<table>
<thead>
<tr>
<th>GS1-128</th>
<th>ITF-14</th>
</tr>
</thead>
<tbody>
<tr>
<td>(01) 1 9501101 53000 0 (17) 140704 (10) AB-123</td>
<td>19501101530000</td>
</tr>
</tbody>
</table>

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GS 1 Standards

Identify: GS1 Standards for Identification

GLN Global Location Number  GTIN Global Trade Item Number  SCC Serial Shipping Container Code  GRI Global Returnable Asset Identifier  GI Global Individual Asset Identifier  GSRN Global Service Relation Number

Capture: GS1 Standards for Barcodes & EPC/RFD

GS1 Barcodes

GS1 EPC/RFD

Share: GS1 Standards for Data Exchange

Master Data Global Data Synchronisation Network (GDSN)  Transactional Data Electronic Data Interchange (EDI)  Event Data EPC Information Services (EPCIS)

Interoperability

Item Master Data  Location Data  Item/Shipmen Tracking  Traceability  Product Recall/Withdrawal  Pedigree  Purchase Order/Despatch Advice/Invoice

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Global Trade Item Number (GTIN) is used for the unique identification of trade items worldwide and in the healthcare industry; the integrity of these numbers throughout the lifetime of the item is a key to maintaining uniqueness across the whole supply chain.

A change in one aspect, characteristic, variant or formulation of a trade item may require the allocation of a new GTIN.
Standardisation

- GS 1 vs in-house systems
- How many have taken up GS 1 as their standard?
- How many are using in-house systems?
- What other approaches are being taken?
- Challenges?
Definition:

“The provision of a complete investigational medicinal product (IMP) label on an electronic device whilst utilizing some type of single panel label on the physical packaging”

Source: Transcelerate: https://www.transceleratebiopharmainc.com/initiatives/elabels/#
What constitutes an eLabel?

- **Mobile Device**
  - Push – system pushes the label to the patient device on enrolment
  - Pull - systems retrieves label by scanning barcode on a patient kit

- **LCD Display**
  - Faubel MedLabel
Challenges...?

- Uptake
- Acceptance
- Regulatory
- Technology
Transcelerate Proposal

**eLabel on smart phone** + **Universal pictogram paper label on kit**

**Universal Label Content Drivers:** Safety and Dispensing

![eLabel on smart phone](image1)

**PROTOCOL NR**
ETRIAL001

**DOSSING INSTRUCTIONS**
Push out 1 morning capsule and 1 evening capsule

**EXPIRY DATE**
04-2017

**SUBJECT ID**
1001

**INVESTIGATOR**

**DESCRIPTION**
1 Kit with 3 smartblister, each containing 24 placebo capsules for push out only (no intake).
Keep product in original packaging until dosing. Store between 2-8°C. Keep out of reach of children.
Please return empty packaging and unused products.

**MEDICATION NR**
123456789123

**REFERENCE NR**

![Universal pictogram paper label on kit](image2)

Company Name

www.companyclinicaltrial.com 184736903
References

1. Transcelerate:

https://www.transceleratebiopharmainc.com/initiatives/elabels/#

2. The Near-Term Viability and Benefits of eLabels for Patients, Clinical Sites, and Sponsors:

Jodi Smith-Gick, RPh; Nicola Barnes, MSc; Rocco Barone, BSc; Jeff Bedford, BSc; Jason R. James, BSc; Stacy Frankovitz Reisner, MPh; and Michael Stephenson, BSc

3. GS 1:

https://www.gs1.org/industries/healthcare/clinical-trials