

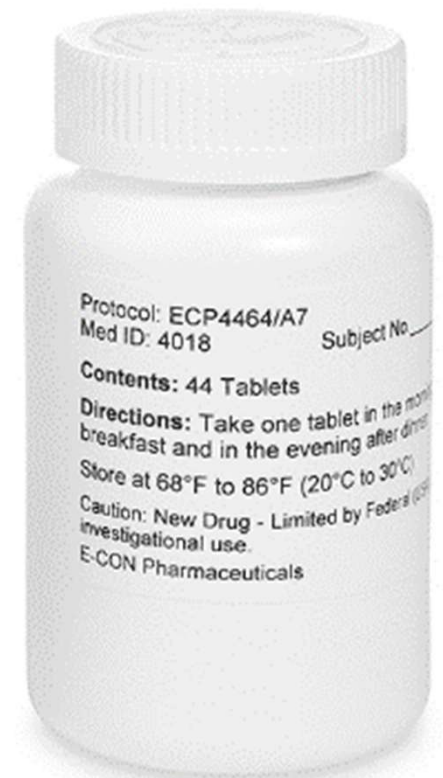
# Digital Labels in Clinical Supply

Alexander Debets  
Former MSD





“Every medication kit needs a label,  
....  
can we make an electronic label?”



# Paper Labels for IMP

## Challenges:

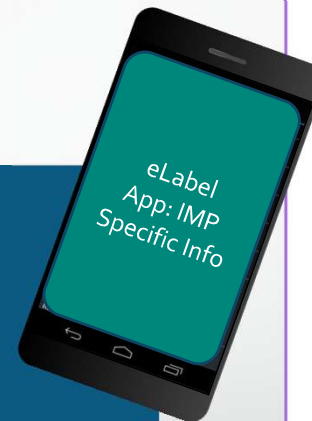
- Static content
- Restricted space
- Development & production lead time
- Waste
- Delays



# Electronic-Label for IMP




- The TransCelerate eLabels workstream started in 2015 to progress digitally supported labels.
- As of January 2021, the eLabels Initiative was completed. No new deliverables or updates.




## STORAGE

 Store in refrigerator (2–8°C)


## HANDLE WITH


 Dilute before use

## ADMINISTRATION

 Injectable product

## WARNINGS

 Do not drive or operate machinery

 Not for use in pregnancy

IMP Agnostic Info

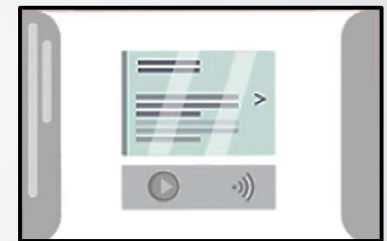
# Electronic-Label vs Digital Display Label (DDL)

## EU Guidelines to Good Manufacturing Practice Medicinal Products for Human and Veterinary Use Annex 13 Investigational Medicinal Products

*Detailed Commission guidelines on GMP for IMPs for human use"  
published December 2017*

The particulars listed in Article 26 should **appear on the primary packaging and on the secondary packaging** (except for the cases described in Articles 29 and 30).

*If it becomes necessary to change the expiry date, an additional label should be affixed to the IMP. This **additional label should state the new expiry date and repeat the batch number and clinical trial reference number**. ... The re-labelling operation should be performed by appropriately trained staff in accordance with **GMP principles** ...*



- ✓ Information visible w/o QR and device
- ✓ Regulatory required + supplemental information
- ✓ For IMP
- + Additional technology

# Clinical Supply Labelling 2026



The screenshot shows the GOV.UK website page for 'Clinical trials for medicines: labelling'. The page title is 'Clinical trials for medicines: labelling' under the 'Guidance' section. The breadcrumb trail is 'Home > Health and social care > Medicines, medical devices > Clinical trials and investigations'. The page content includes 'Guidance on labelling for medicinal products used in clinical trials.' and a red circle highlighting the text 'These amendments come into force on 28 April 2026'. At the bottom, there is a link to 'Medicines and Healthcare products Regulatory Agency Clinical trials for medicines: labelling - GOV.UK'.

In most cases, if an IMP to be used in a clinical trial is not authorized ..., **it must be labelled with the following information, per regulation 46(1) of the Clinical Trials Regulations:**

- .....
- information related to the use of the medicinal product, including
  - instructions for use (which may be by reference to a patient information leaflet) or administration
  - method or route of administration
  - **expiry date**
  - any special storage precautions

....

The labelling information above is generally expected to be **applied to the primary packaging ....**

# eLabel Commercial $\neq$ eLabel Clinical

Electronic product information (ePI) refers to the authorized, statutory product information for medicines adapted for handling in electronic format ... [EMA]



# E-Paper Displays



Source: <https://www.eink.com/application/detail/ESL>



Source: <https://www.eink.com/showcase?cate=ereader>

# DDL: Minimum Viable Product

Minimal Viable Product for IMP:

- Meeting Quality and Regulatory requirements
- ERP Integrated
- Remotely updateable, multiple pages off-line
- Cold Chain ready
- Enabling additional features
- Vial as packaging configuration



# DDL: Vial Concept Solution



Smurfit  
Westrock

Cere® Screen Digital Display Label

I. Component ID: WRK54321  
II. Participant Number = PN:  
WRK12345  
III. Lot Trace ID: W037810  
IV. MK-WXYZ 100mg  
V. 1 vial - 5 mL  
VI. Protocol MK-WXYZ-001  
VII. Use by End:  
08/2023 - 2023/08/31 - 31/08/2023



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Courtesy of Smurfit WestRock, ECCT and MSD

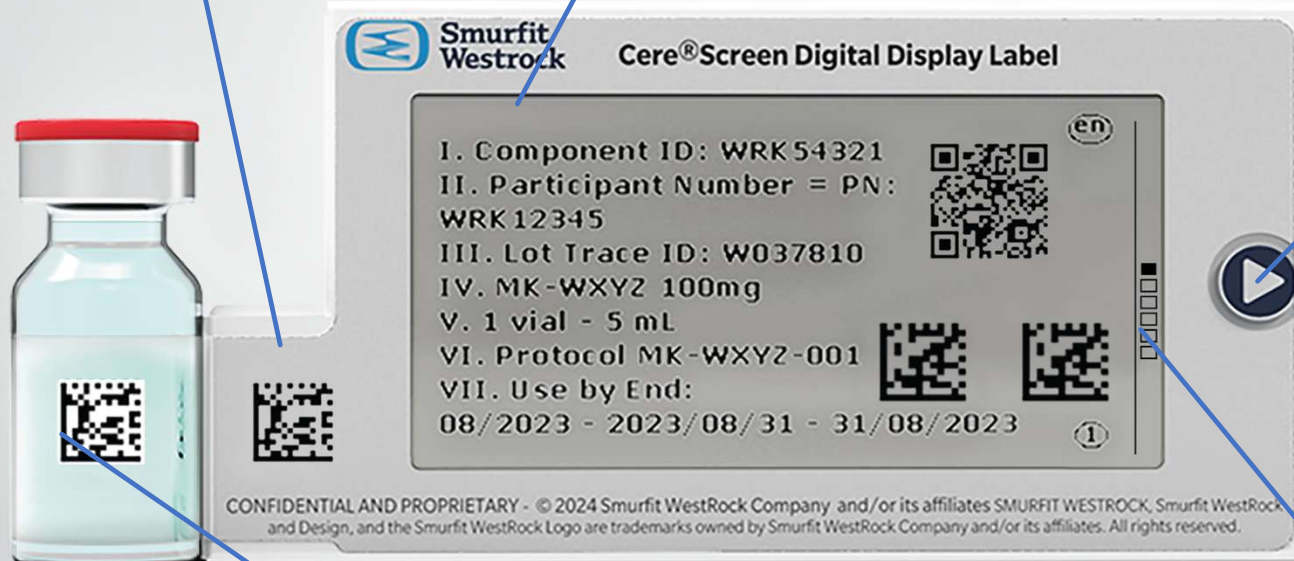


# DDL: Vial Concept Solution

Extension permits vial adaptors CSTDs

E-paper display

- Not shown:
- Battery
  - Microprocessor
  - NFC antennae



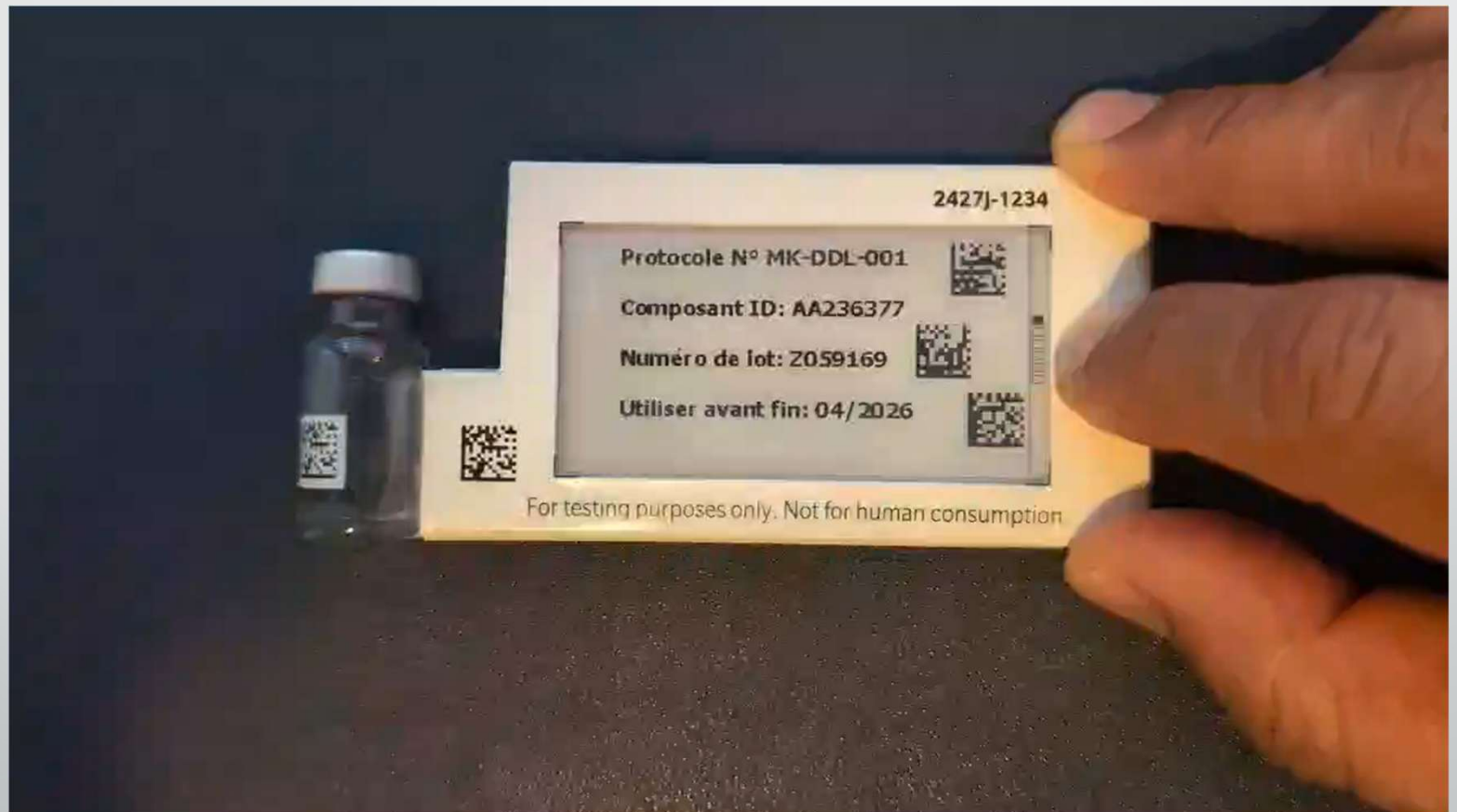
Button advances pages, sets home screen accesses test mode

Navigation bar

Flag label secures to vial

Courtesy of Smurfit WestRock, ECCT and MSD

## DDL: Multiple-Page "Page Flip"



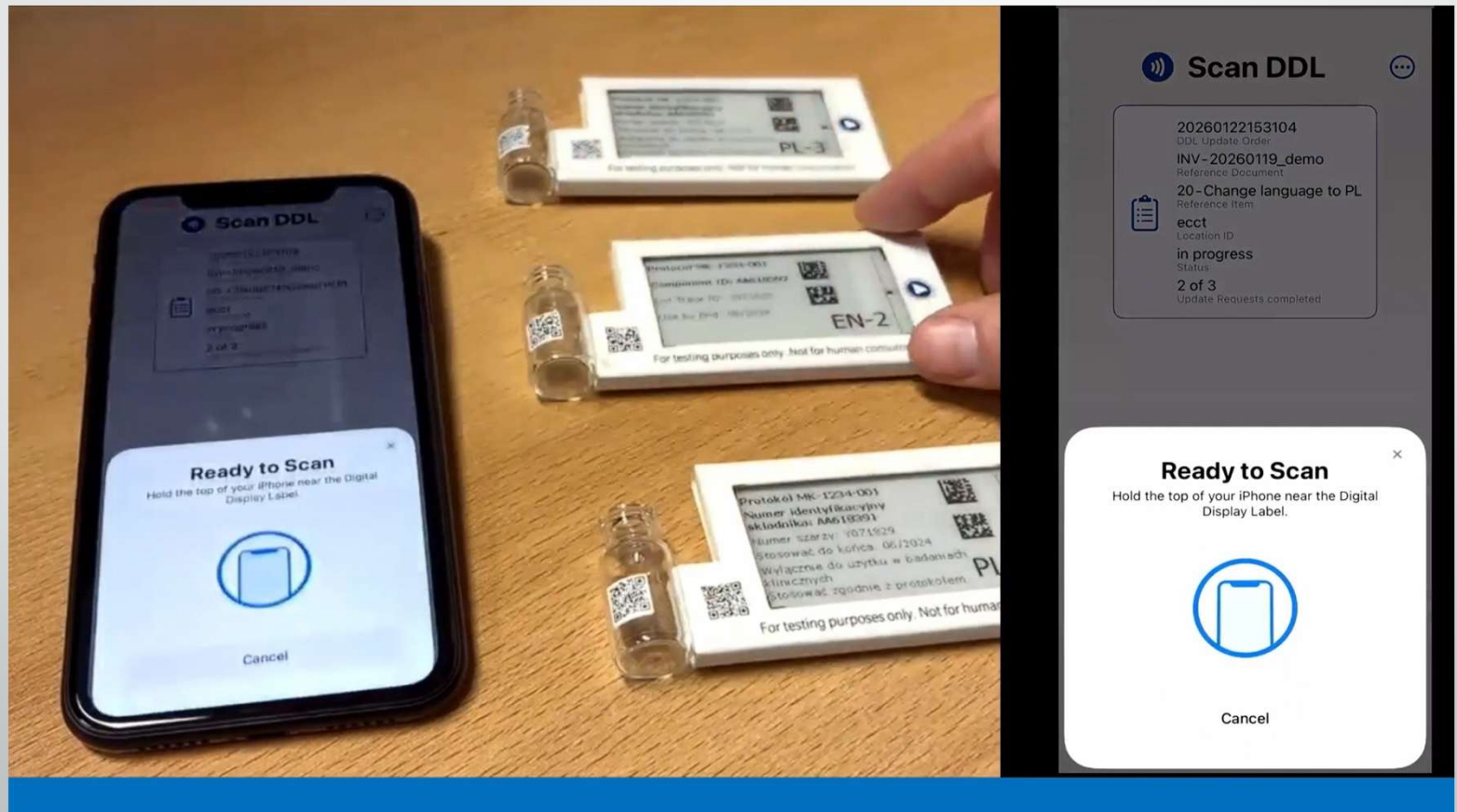
*Courtesy of MSD*

## DDL: Remote Label Up-date by Reader



*Courtesy of MSD*

# DDL: Remote Label Up-date by Mobile Device



Courtesy of ECCT

# DDL: Capabilities

## STAND ALONE

- ✓ Easy and on-demand remote updates: label updates, address changes, etc.
- ✓ Process accelerations up to 60%
- ✓ Improved flexibility and traceability, audit trail
- ✓ Remote updates in sealed package/ container
- ✓ Re-usable/Re-cyclable solution
- ✓ Including IoT solutions

## ERP INTEGRATED

- + Global Connected Systems, EtE: Pooling, IRT, Inventory Management, Scheduling Systems, IoT sensors, ...
- + Global Regulatory, Quality & Compliance: G(x)P qualification, audit trail, QA, ...
- + Real-time across Global Network: Multiple Countries, Multiple Sites, Multiple Trials, ...



# DDL Clinical Customers Experience

## 2023-2024 Human Factor Studies

(>45 Patients, Nurses, Pharmacists, Etc.)

- ✓ DDL legibility and readability comparable to paper
- ✓ Navigation clear
- ✓ Successful use of CSTD and needles
- ✓ Safe dose preparation
- ✓ Additional benefits

## 2025 (June) Pilot Clinical Trials

(>40 kits)

- ✓ Quality: no challenges, with improvements and benefits to paper
- ✓ Speed: >25% cycle time reduction
- ✓ Clinical Site Full-Satisfaction: 80%

>> "Digital Display Labels in Clinical Trials: From Concept to Practice" – ISPE paper summer 2026

# DDL Industry Collaborations

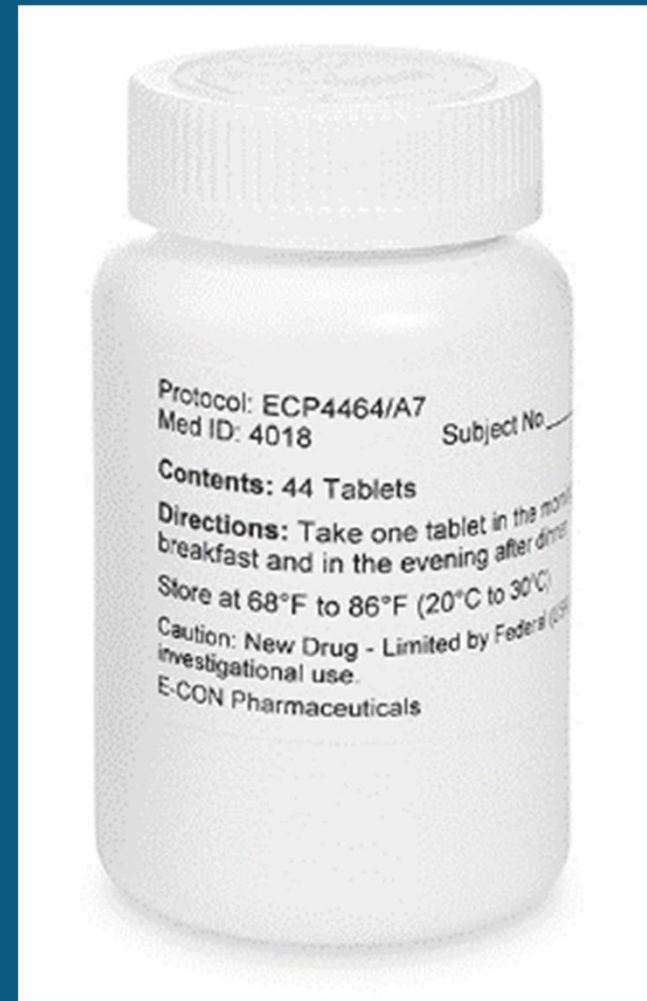
Harmonizing on the industry application of DDL for patients, health authorities, clinical sites, and sponsors:

- Position Papers
- URS alignments
- User Experiences
- HAs engagement
- DDL Lifecycle Management Strategy



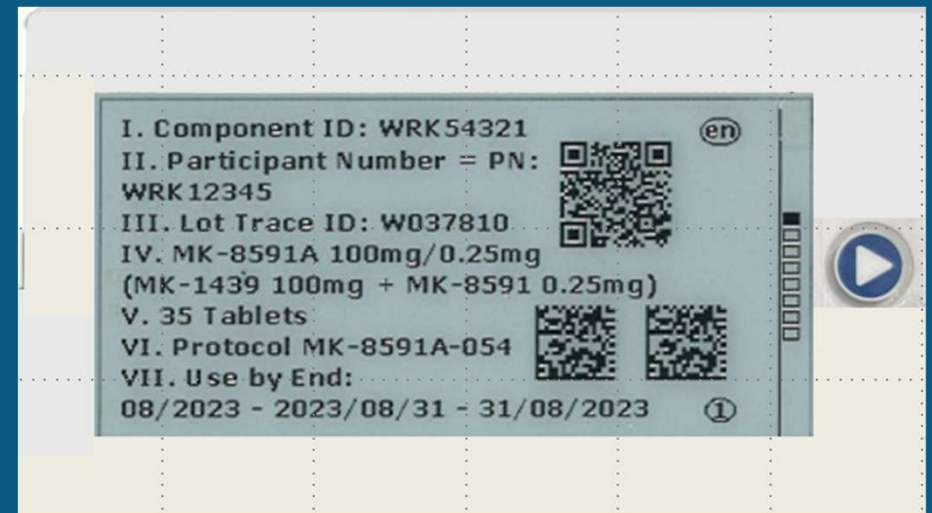
Martina Marauli (MSD) <[martina.marauli@msd.com](mailto:martina.marauli@msd.com)>  
Dejanira Araiza Illan (J&J) <[daraizai@its.jnj.com](mailto:daraizai@its.jnj.com)>

“Every medication kit  
needs a label,...

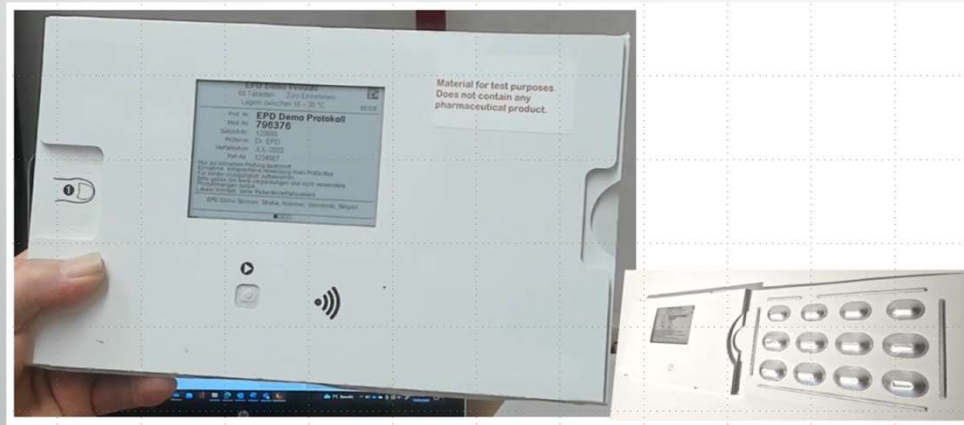


“Every medication kit  
needs a label,...

... with DDL creating  
unique opportunities  
to digitize  
information for  
patients and  
stakeholders”



# Future DDL Extended Label Applications



Courtesy of ECCT

# Future Medication Tracking and Monitoring

From Box



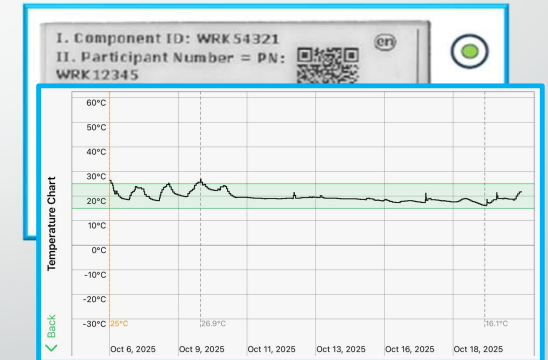
*Courtesy of Sensitech*

To Kit Level, Separated



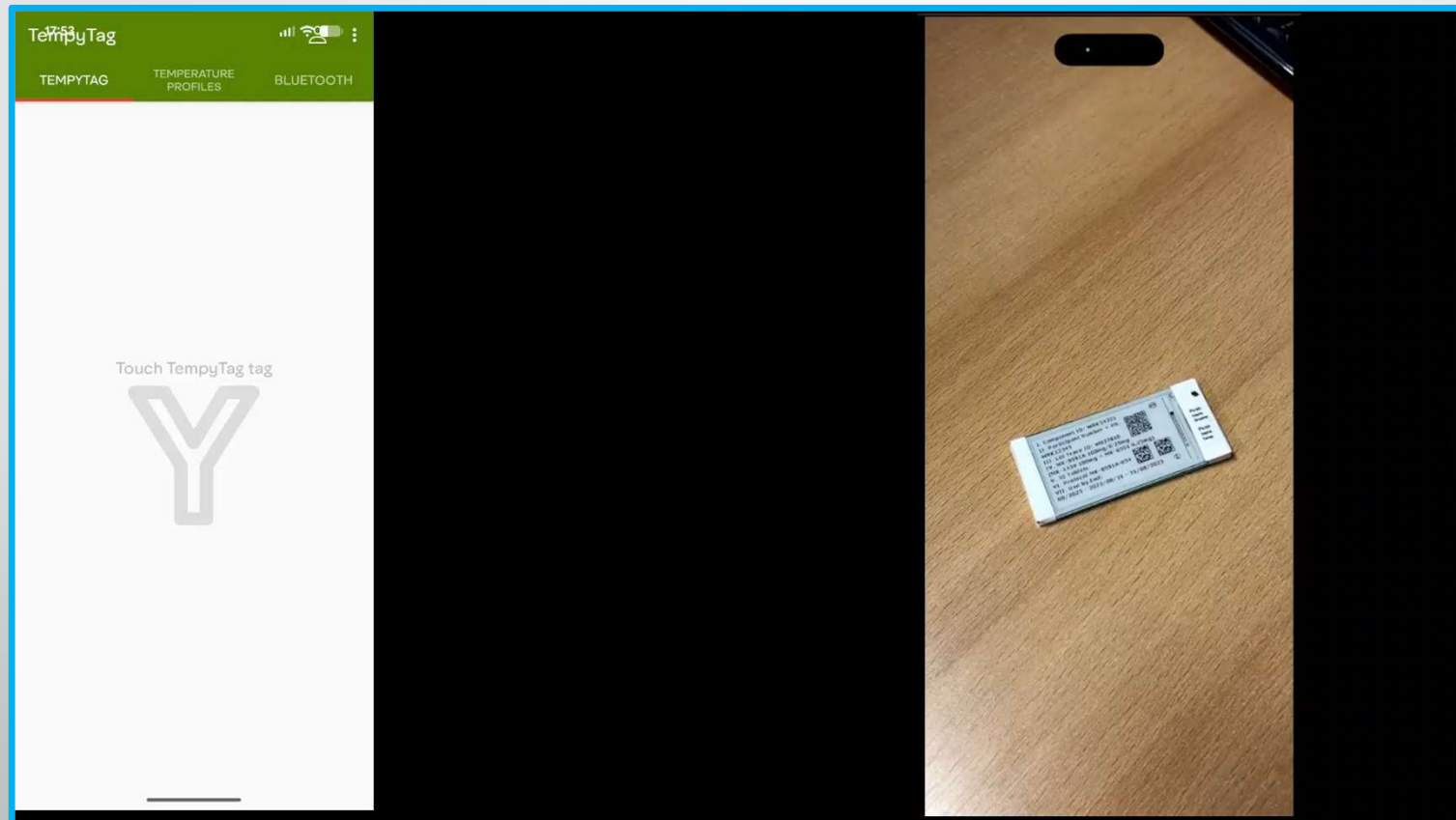
*Courtesy of Elpro*

To Kit Level, Integrated



*Courtesy of ECCT*

# Medication Temperature Monitoring with DDL



Courtesy of ECCT

# Future Medication Adherence



**Electronic Dosepak®**



**Cerepak®**

*Courtesy of Smurfit Westrock*

**Smart Packaging & Labeling**



# Future Medication Extended Label Information

Loud speaking



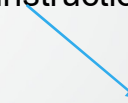
I. Component ID: WRK54321  
II. Participant Number = PN: WRK12345  
III. Lot Trace ID: W037810  
IV. MK-8591A 100mg/0.25mg  
(MK-1439 100mg + MK-8591 0.25mg)  
V. 35 Tablets  
VI. Protocol MK-8591A-054  
VII. Use by End:  
08/2023 - 2023/08/31 - 31/08/2023

en

Speaker icon

Play button icon

Animation / instructions



< Back Dosing Details

DOSE DETAILS

Maximum	28
Current	12
Removed	17

REMOVED DOSES

- Sunday, 26 January 2025 at 20:27
- Wednesday, 26 February 2025 at 06:42
- Thursday, 27 February 2025 at 04:10
- Friday, 28 February 2025 at 02:35

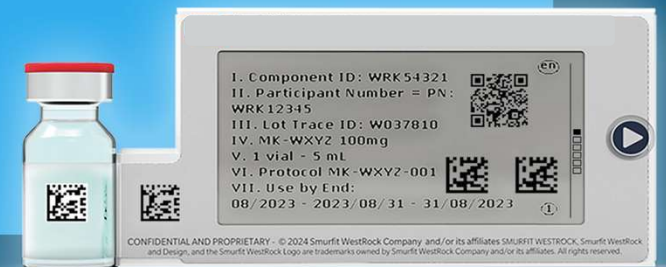
Video player icon

Play button icon

Courtesy of ECCT

# We are building a roadmap,... but The Future is Now!

- ✓ Commercial products available
- ✓ No quality challenges, with improvements and benefits to paper
- ✓ Reducing drug-waste and production
- ✓ High Clinical Site satisfaction
- ✓ Improved drug Inventory: Pooling
- ✓ Reduced cycle-times and less shipments
- ✓ ERP integrated and Stand-Alone solutions
- ✓ Sustainable



# Thank You



Acknowledgement:  
DDL Project Lead Martina Marauli (MSD), [martina.marauli@msd.com](mailto:martina.marauli@msd.com)

## REFERENCES

**“Digital Display Labels in Clinical Trials: From Concept to Practice”** – This paper is a follow up-on the 2024 industry position article, describing a minimum viable product (MVP), operational, clinical and regulatory results. Summer 2026.

**“Digital Display Labeling in Clinical Supplies for Clinical Trials”** – This article introduces DDLs for the clinical supply chain, with a roadmap of prototypes, the regulatory context, business value, technology background, and software-hardware integration requirements.

**Link:** <https://ispe.org/pharmaceutical-engineering/march-april-2024/digital-display-labeling-clinical-supplies-clinical>

**“Digital Display Labels Set to Transform the Clinical Supply Chain”** – This article reflects on the presentation of DDLs at the AIPIA & AWA Smart Packaging Congress, showcasing examples of prototypes.

**Link:** <https://www.packworld.com/trends/digital-transformation/article/22926914/merck-and-jj-partner-on-digital-display-labels-for-clinical-trials>

**“Through the Line Podcast: Digital Display Labels”** – This podcasts talks about the latest technologies in healthcare packaging, especially DDLs, with emphasis on the challenges that DDLs help overcoming in the context of clinical trials.

**Link:** [https://www.healthcarepackaging.com/design-materials/package-design/podcast/22937413/through-the-line-podcast-digital-display-labels?utm\\_source=Newsletters&utm\\_medium=HCP+Newsletter&utm\\_term=20250416&oly\\_enc\\_id=2804G9462578C1V](https://www.healthcarepackaging.com/design-materials/package-design/podcast/22937413/through-the-line-podcast-digital-display-labels?utm_source=Newsletters&utm_medium=HCP+Newsletter&utm_term=20250416&oly_enc_id=2804G9462578C1V)