Norwegian Medical
Products Agency

GIDWG-møtet i Sao Paulo

Oppsummering for prosjektstyret og deltakere i SAFEST-prosjektet, samt andre interessenter

10.10.2024
Elin May Merry, Bernd Moeske og Kristine Aasen

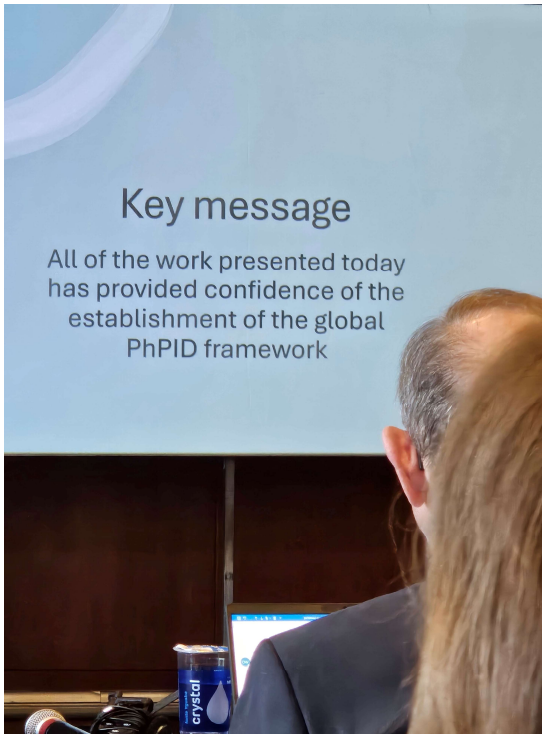
GIDWG – Global IDMP Working Group

- **GIDWG ble etablert i 2021**
  - Som et resultat av en IDMP-workshop arrangert av WHO, Geneve, sept. 2019
  - Støttet av samarbeidsrammeverket for IDMP mellom EMA og FDA
- **Formålet med GIDWG**
  - Hvordan ISO IDMP kan implementeres globalt
- **Medlemskap**
  - Stiftende medlemmer: **EMA**, **FDA**, and WHO/**UMC**;
  - Regulatoriske medlemmer: **Health Canada**, **ANVISA** (Brazil), **SwissMedic** (CH), **Saudi FDA**, **NOMA** (Norway);
  - Industrimedlemmer: **IFPMA - International Federation of Pharmaceutical Manufacturers and Associations**
- **GIDWGs mål**
  - Utvikle og gjennomføre prosjekter som demonstrerer at IDMP standardene bør implementeres globalt
  - Utvikle rammeverk, regler og modeller for global implementering og vedlikehold av globale identifikatorer for legemidler

Program og agenda

	9. sept.	10. sept.	11. sept.	12. sept.
Agendapunkt	Åpningstaler Regler for PhPID generering: substanser, legemiddelformer, styrke	Regler for PhPID generering: substanser, legemiddelformer, styrke Bruk av FHIR til forespørsel/tildeling av PhPID Testingen og resultater	Hvor klare er vi for IDMP, utfordringer og muligheter	Rapport fra testingen; harmonisering, Identifikatorer, HL7 FHIR
Deltakere	Medlemmer	Medlemmer	Industri og regulatorisk virksomhet	Alle interessenter
Presentatører	WHO, WHO-UMC, FDA, EMA	WHO, WHO-UMC, FDA, EMA	FDA, EMA, ANVISA, Swissmedic, Health Canada, DMP, IFPMA, repr. fra industrien	FDA, ANVISA, AstraZeneca, EMA, WHO-UMC, WHO

Presentasjoner og gruppearbeid

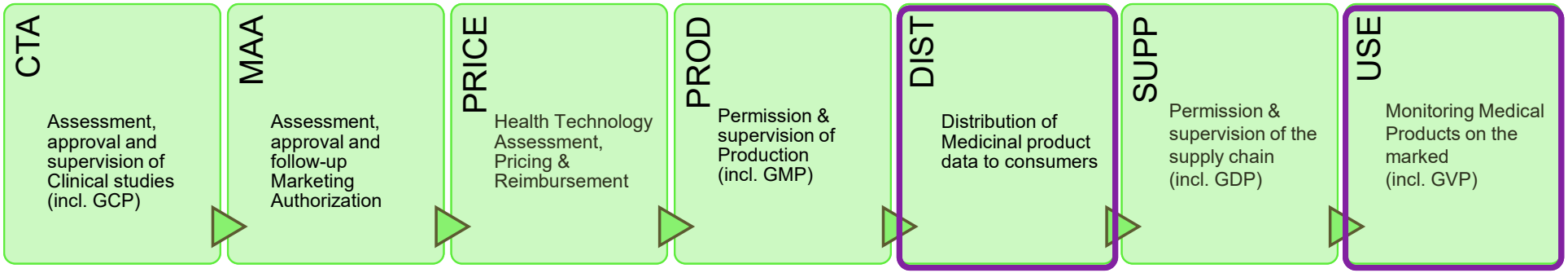


The Norwegian Medical product Agency (NOMA)

NOMA is the national competent authority of Norway

- 360 employees
- Located in Oslo
- Responsible for medicinal products, medical devices, blood, cells and tissues, narcotics and homeopathic
- Distributes data on 9000 medicinal products both with and without marketing authorisation
- The mission is ensuring that people have equitable and timely access to effective medicines of high quality to the lowest possible price

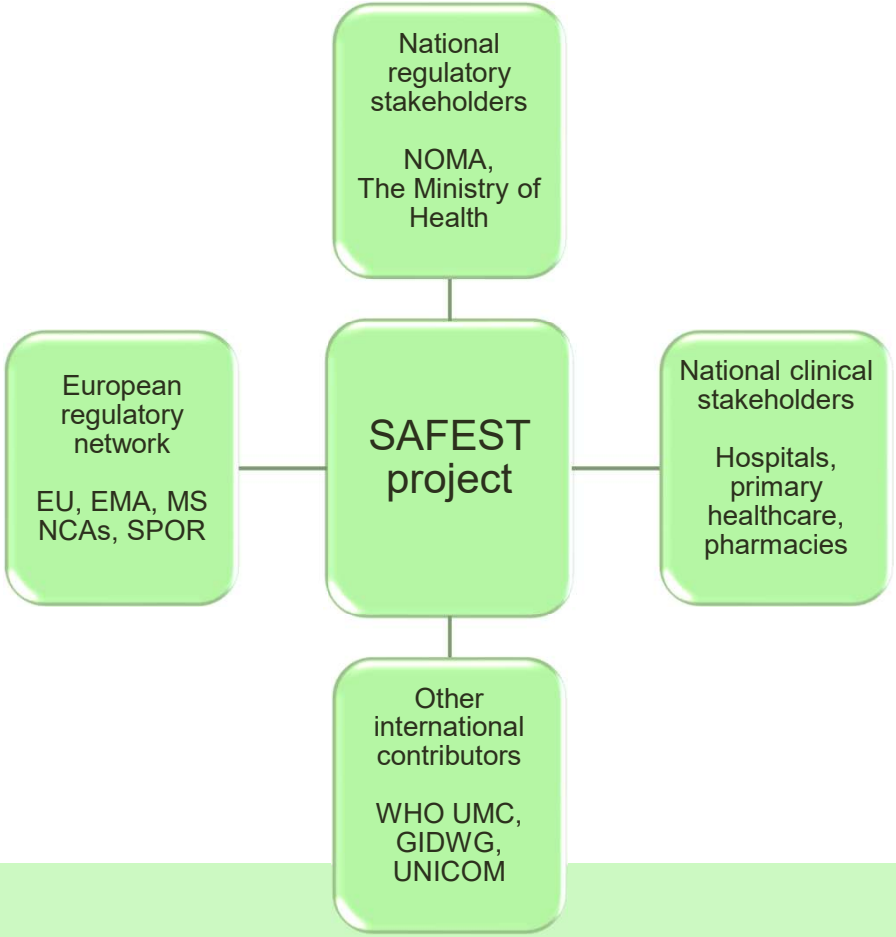
NOMA's Value Chain



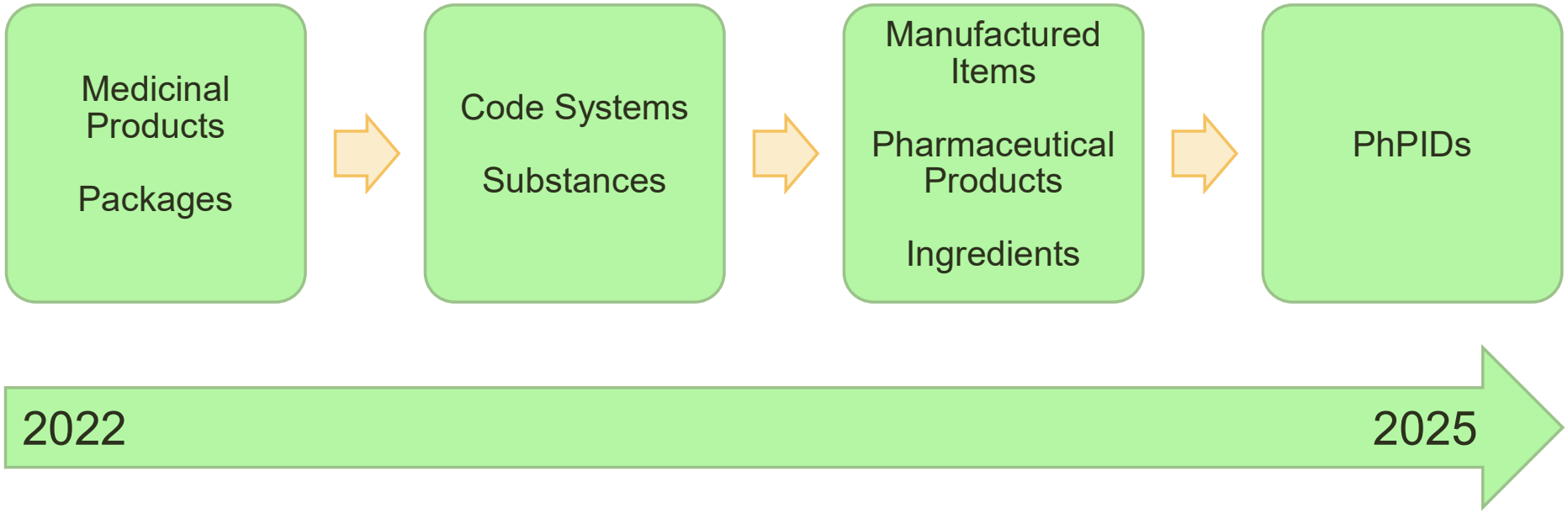
NOMA's SAFEST project, - Getting to IDMP

Collaboration with different stakeholders

- National and international actors
- Regulatory and clinical domain



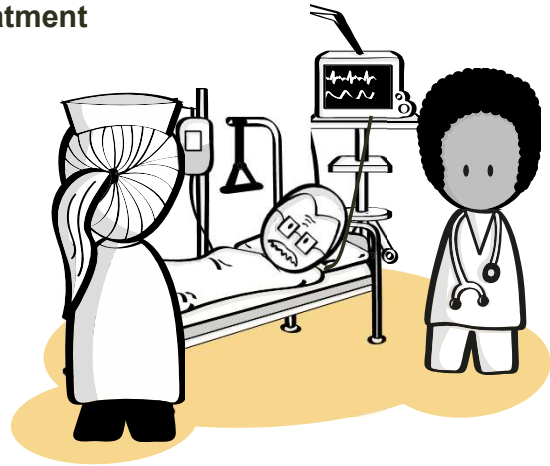
SAFEST deliverables timeline



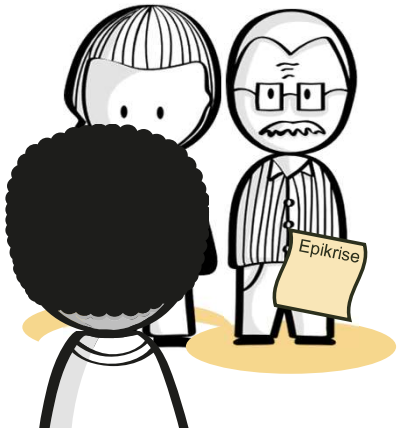
Use Case: The value of PhPID in hospital healthcare

1 **Patient admission, anamnesis and medication reconciliation**

2 **Plan and complete medical treatment**



3 **Finish treatment and discharge**



Prescription based on….

Package / PhPID level 4	PhPID level 3	PhPID level 4
substance + dose form + strength	substance + dose form	substance + dose form + strength

Thomas arrives at hospital with chest pain

1 Patient admission, anamnesis and medication reconciliation

Thomas, aged 62, arrives at the hospital with increasing symptoms of known heart failure. He had a heart attack two years ago.

He has brought his current medication for heart failure prevention.

The doctor conducts a medication reconciliation

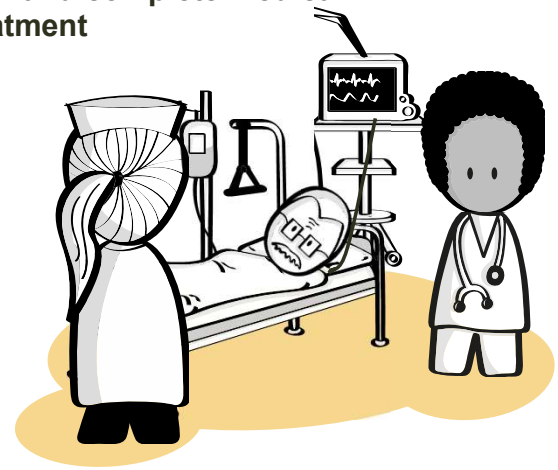
1 **Patient admission, anamnesis and medication reconciliation**

The doctor retrieves Thomas's medication record from the E-prescription system. He confirms the product details and reviews the PhPID level 4 specifying the substance, dose form and strength.

He then admits Thomas to the cardiology ward for further treatment

Thomas is admitted to the ward and his medication list is transferred to the electronic medical record system

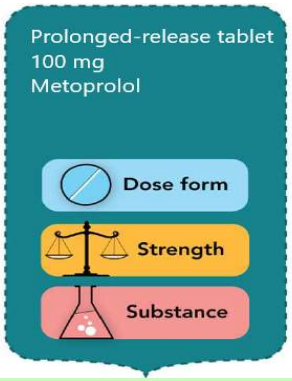
2 Plan and complete medical treatment



At the hospital ward Thomas will continue to receive his home medication.

His medication is converted to PhPID level 3 and transferred to the electronic medical record to monitor treatment during his stay.

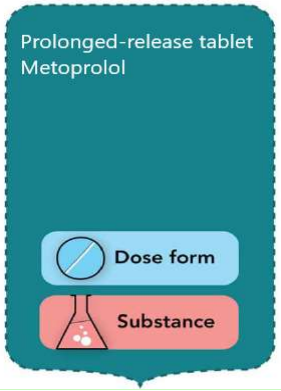
Electronic Health Record system
PhPID level 4



Dosage:
1 tablet,
1 x per day

converting

Dosage:
100 mg,
1 x per day

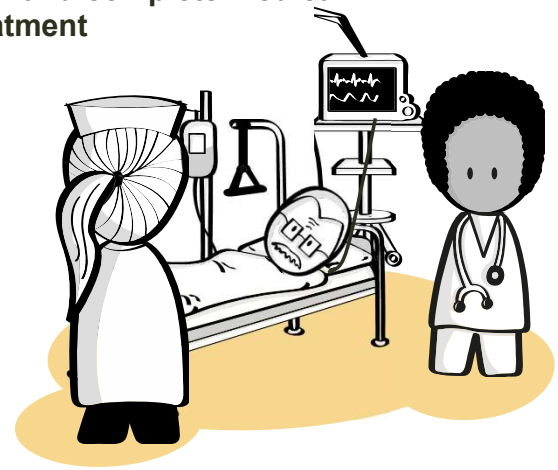


electronic medical record system

PhPID level 3

The nurse dispenses and administers the medication

2 Plan and complete medical treatment



The medicine room stocks only 50 mg prolonged-release tablets under the brand name Bloxazoc, a generic equivalent of Selo-Zok.

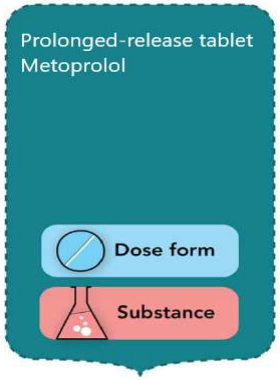
Bloxazoc shares the same PhPID level 3 as Selo-Zok, meeting the hospital's prescription requirements.

The nurse scans the 50 mg Bloxazoc package, and the system indicates that 2 tablets should be given to Thomas.

The nurse then administers the medication.

PhPID level 3

Dosage:
100 mg,
1 x per day



Both Selo-Zok 100 mg and Bloxazoc 50 mg can be used

Before hospital discharge, the doctor issues a new prescription with an increased strength

3 **Finish treatment and discharge**

The hospital doctor increases the medication dose from 100 mg to 200 mg.

To simplify administration for Thomas at home, the tablet strength is increased to 200 mg so that he can continue taking 1 tablet every morning.

The doctor creates a new prescription based on PhPID level 4, detailing the substance, dose form, and strength.
The prescription is then transferred to the national E-prescription system.

Thomas picks up the medication at the pharmacy

3 **Finish treatment and discharge**

The pharmacist tells Thomas he can choose from three different brands with the same clinical effect.

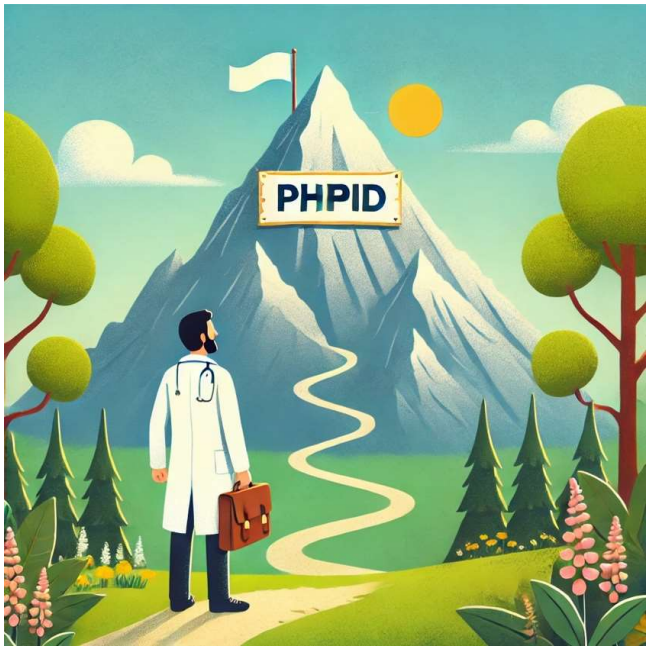
According to the national reimbursement scheme, the cheapest brand is free, but he can pay extra for another brand. Thomas chooses the free option.

The benefits of using PhPID in hospital healthcare

- The national goal is to increase the use of substance-based prescriptions, based on PhPID, to **improve flexibility and reduce medication costs** at pharmacies
- PhPID level 3 in hospitals **improves flexibility and saves nurses time** by allowing them to dispense available medicines with the same clinical effect
- **Improves efficiency for doctors** by reducing the need to change prescriptions when certain strengths are out of stock
- **Patient safety is ensured** through the hierarchical structure of PhPID levels 3 and 4.
- Standardization with PhPID as the national and global identifier for substance-based prescriptions **increases safety and system interoperability**

Medicinal Product Dictionary at NOMA: From Proprietary to IDMP and PhPID

- Our “Recipe” for getting to IDMP and PhPIDs
- Spotlight:
  Harmonizing Pharmaceutical Products
- Collaboration with UMC:
  Global and National PhPIDs
- Status and Roadmap



Getting to IDMP: A Gradual, Step-by-Step Process

Our “recipe” for transitioning from a proprietary product database to an IDMP-based Medicinal Product Dictionary and PhPID

Collaboration with WHO UMC

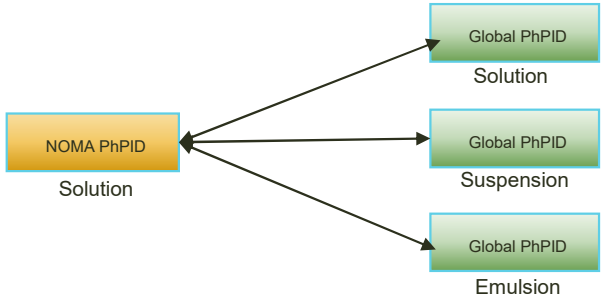
Tight collaboration with UMC has been a key success factor in our journey.

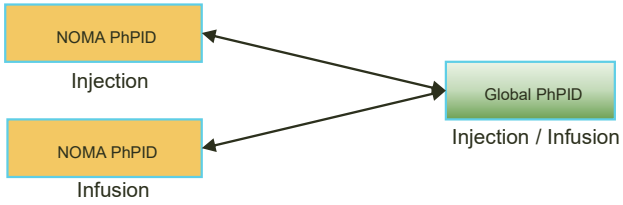
UMC and NOMA expect and accept that national and global PhPIDs may differ in some instances.

However, we do not anticipate that these differences will significantly impact the value of the PhPIDs for their respective use cases.

National and Global PhPIDs at NOMA

- NOMA has established business rules for PhPID generation and developed a PhPID generation tool to validate the results.
- We are currently testing UMCs global PhPID service API and a gap analysis is planned for Q4 2024.
- Our medicinal product dictionary will contain both national and global PhPIDs which will be mapped according to the specific use cases and scope.





Roadmap: Transitioning to IDMP/FHIR in Norway

Publishing National MPD (2022- 2025)

Distribute ISO IDMP-compatible national master data on medicinal and nutrition products.

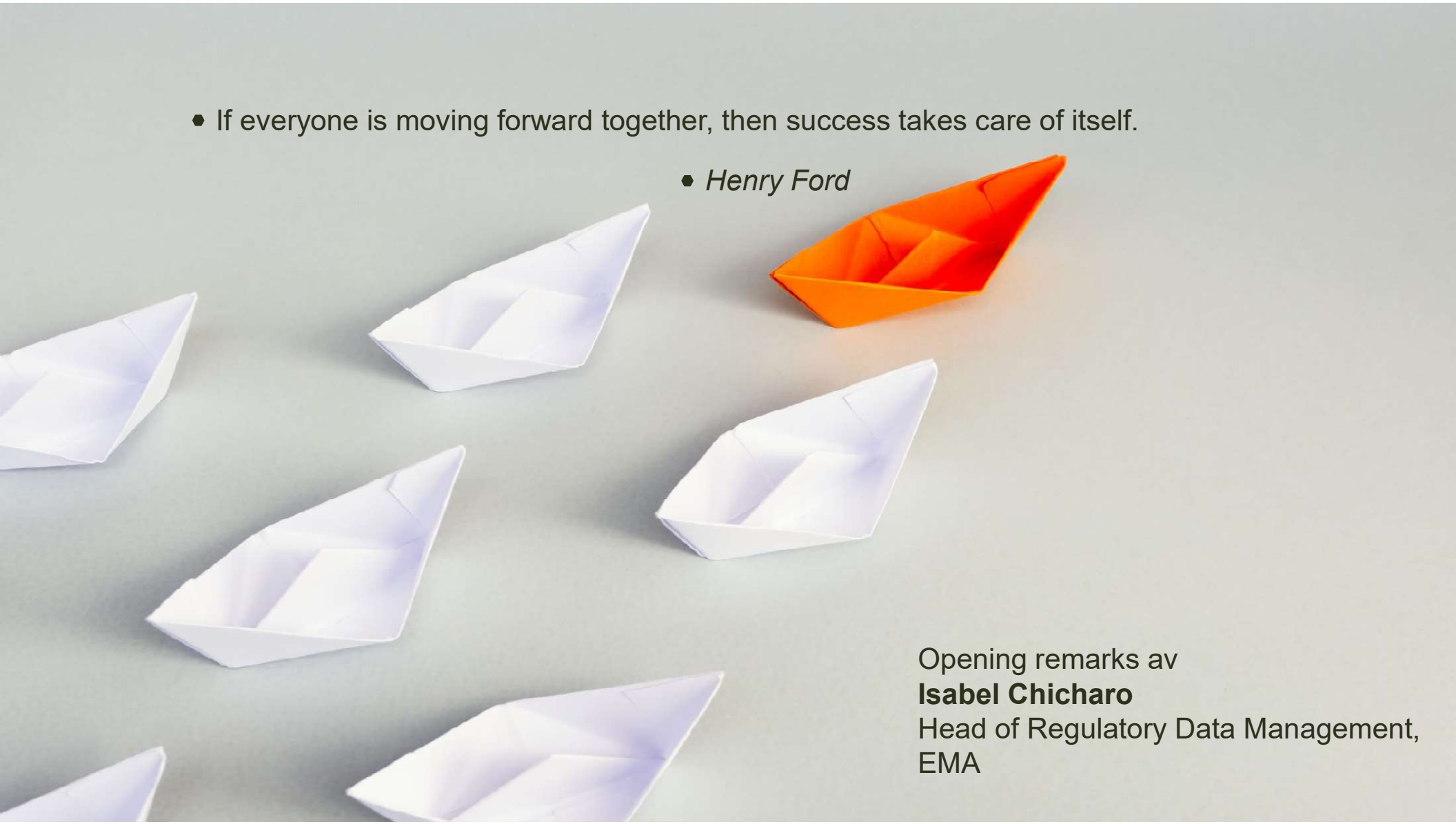
Including national and global PhPID sets.

National transisitoning to IDMP and FHIR

Gradually transitioning from proprietary MPD and transaction data to ISO IDMP, FHIR and national PhPIDs

Enabling international data exchange using IDMP

Enabling the exchange of medication-related data with international stakeholders, based on ISO IDMP, FHIR and global PhPIDs.



Opening remarks av
Isabel Chicharo
Head of Regulatory Data Management,
EMA

PhPID – Use cases and legal references

Substance

Strength

Adm Dose Form

Pharmacovigilance

- Dir 210/84/EC, Rec(35)
- Dir 2001/83/EC, Art 108(c)
- Commission implementing Reg EU No 520/2012, Rec; Art 25(1) and Art 26(1)
- ICH E2B (R3) guidance
- EU Individual Case Safety Report (ICSR) Implementation Guide

Drug Shortages

- Council Regulation (EU) 2022/123, Art 13.6 (b) ***ISO IDMP*** and SPOR

Cross border prescription

- Guidelines on ePrescription dataset for electronic exchange under cross border Directive 2011/24/EU – Release 3 – ISO IDMP standards and ISO 11616:2012

Deus Mubangizi
Director Health Products Policy and Standards (HPS),
Access to Medicines and Health Products Division (MHP)

World Health Organization

- **WHO/MHP and UMC management** met, discussed and agreed on this position on 20th June 2024, and there have been several exchanges on the same since.

- GIDMP (GSID and PhPID) shall be governed by WHO and run by UMC:
  - ✓ Uppsala Monitoring Centre (UMC), which hosts the WHO Collaborating Centre for International Drug Monitoring, will be responsible for the day-to-day operations of the GIDMP (validation/assignment and technical support) under the oversight of WHO through a WHO appointed Expert Group.
  - ✓ The generation and maintenance of GSID and global PhPIDs (GIDMP) will be carried out within policies determined by WHO.
  - ✓ WHO will appoint an Expert Group with responsibility for overseeing GIDMP. The WHO Expert Group should be truly independent with regional and gender balance.
  - ✓ The GIDWG was a transition arrangement, and its GIDMP coordinating activities will be gradually transferred to the a WHO appointed Expert Group.
  - ✓ During this transition, WHO shall be included in all discussions about the GSID and PhPID organized by UMC and/or the GIDWIG.

- The role of the International Nonproprietory Names (INN) needs to be preserved in GIDMP:
  - ✓ By requiring INN as condition of assigning GSID on a substance, when it is under the scope of INN, occurrence of GSID without INN can be avoided.

- GIDMP (GSID and global PhPIDs) will be available and accessible to WHO and members states free of charge.
  - ✓ The use of PhPIDs will be licensed to a cost to others. These license fees will finance the development and maintenance of the global PhPIDs.

- A legal instrument shall be developed to cover the above arrangements with UMC.

Global Impact of IDMP Standards

Ron Fitzmartin, Sr. Advisor, Office of Regulatory Operations, Center for Biologics Evaluation and Research, FDA

Global IDMP Working Group

- **Enhanced Pharmacovigilance:** Improved surveillance and response to substandard and falsified medicinal products globally.

- **Improved Mitigation of Medicinal Product Shortages:** Faster identification of alternative products.

- **Cross-border Healthcare:** Facilitates seamless access to consistent product information and availability across borders.

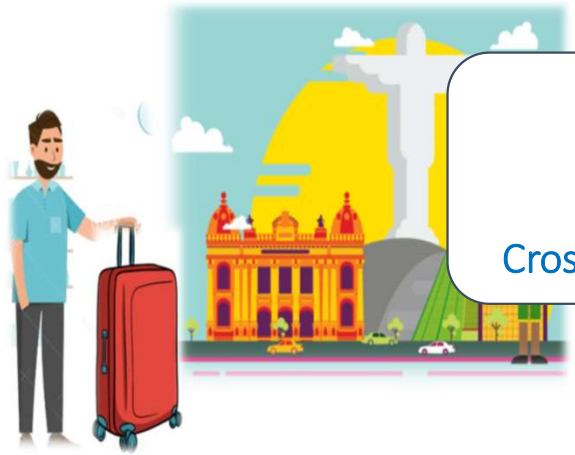
Value of IDMP in the Medicinal Product Life Cycle

Malin Fladvad WHO-UMC

Global IDMP Working Group

Pharmacovigilance

Information Exchange



Cross Border Healthcare

Product Shortages

Malin Fladvad WHO-UMC
GIDWG new members 2024

Saudi FDA

Data validation and analysis started using same criteria as end to end testing

Similar findings identified as for other countries

Direktoratet for medisinske produkter

New use case in hospital health care settings

Implementation of PhPIDs with a national flavour based on global PhPID Business rules

Global IDMP Working Group

End-to-End Testing v/Malin Fladvad, WHO-UMC

PURPOSE:
Testing framework, including business rules, best practices, software and operating model, for the global IDMP implementation and maintenance of global identifiers for marketed products.

SCOPE included both load and stress testing:

•Harmonize medicinal product information and generate PhPIDs for medicinal products based on GIDWG Business Rules

• Selected Substances Dataset (150 substances: various degree of complexity on substances)

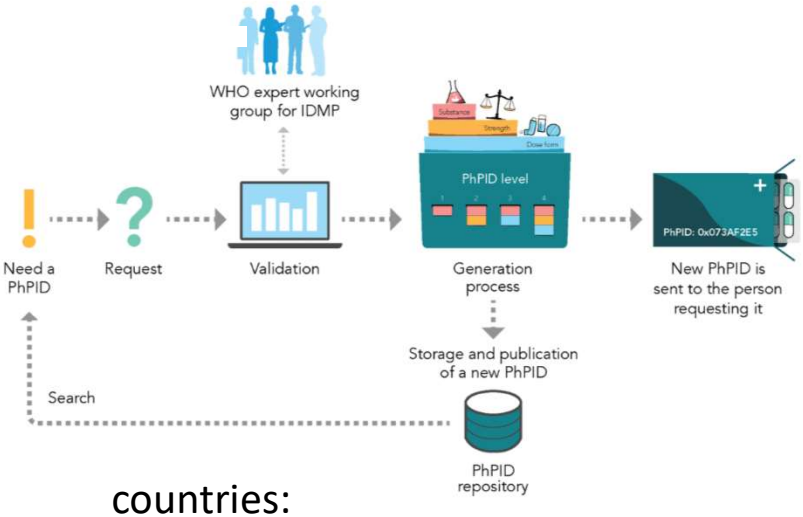
•EDQM + non-EDQM countries

•Similar products from different countries

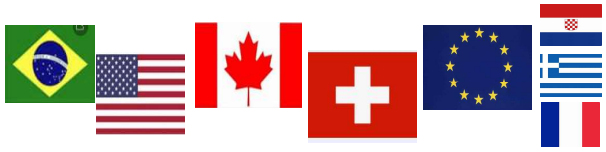
•Larger batches & smaller data sets for regulators

•Testing of Pharmacovigilance, Drug Shortages and Cross-border Healthcare use cases

STATUS: **concluded**



countries:



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Results End-to-End Testing data validation

198 (87%) PhPIDs out of 230 products

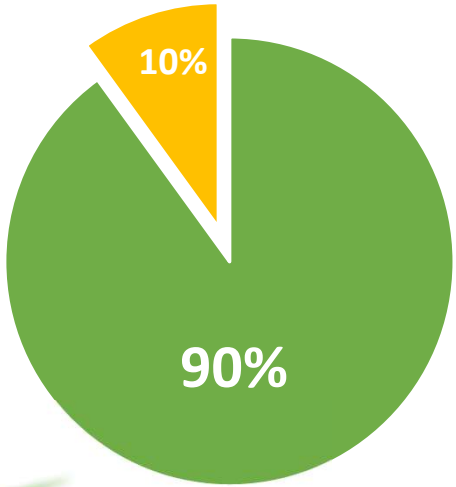
456 (93%) PhPIDs out of 488 products

467 (89%) PhPIDs out of 525 products

678 (90 %) PhPIDs out of 752 products

856 (90 %) PhPIDs out of 952 products

PhPIDs for 2,657 (90%) out of 2,947 **Medicinal Products**



10% of Medicinal Products are part of E2E Findings and are under evaluation

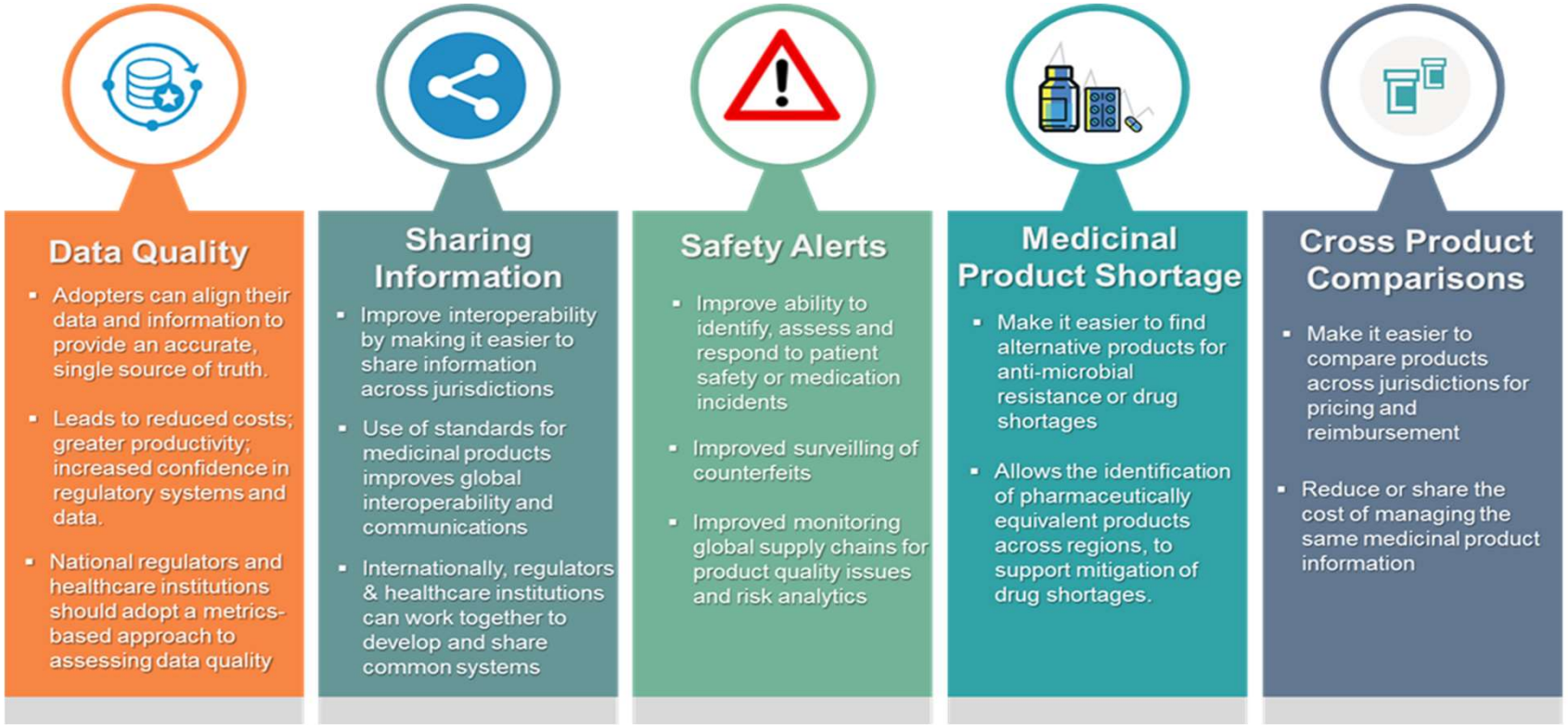
90 % of Medicinal Products have PhPID assigned

Global IDMP Working Group

Key Benefits of IDMP

Global IDMP Working Group

Ta-Jen (TJ) Chen,Office of Strategic Programs, CDER, US FDA



- Cross-regions or global agreement to harmonize on substance ID, representation of dose form, and strength is needed to maximize the benefits

Fra fellesmiddagen

Thank You for your work on IDMP!

Global IDMP Working Group

Referanser:

- About GIDWG – GIDWG
- EU direktiv 2001/83/EC: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32001L0083&qid=1727178213228
- EU direktiv 2010/84/EU 15.12.2010: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32010L0084&qid=1727177770365
- EU forordning 520/2012: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32012R0520&qid=1727178393043
- ICH E2B (R3) Electronic transmission of individual case safety reports (ICSRs) - data elements and message specification - implementation guide - Scientific guideline | European Medicines Agency (EMA) (europa.eu)

  EU Individual Case Safety Report (ICSR)1 Implementation Guide (europa.eu)
- EU forordning 2021/1281 VET: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32021R1281&qid=1727179282883
- eHealth Network Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU ePrescription and eDispensation of Authorised Medicinal Products https://health.ec.europa.eu/document/download/b744f30b-a05e-4b9c-9630-ad96ebd0b2f0_en?filename=ehn_guidelines_eprescriptions_en.pdf
- eHealth Network Guideline on the electronic exchange of health data under Cross-Border Directive 2011/24/EU Patient Summary https://health.ec.europa.eu/document/download/e020f311-c35b-45ae-ba3d-03212b57fa65_en?filename=ehn_guidelines_patientsummary_en.pdf

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Direktoratet for medisinske produkter

Norwegian Medical Products Agency