# Identification of Medicinal Products (IDMP)

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# Overview

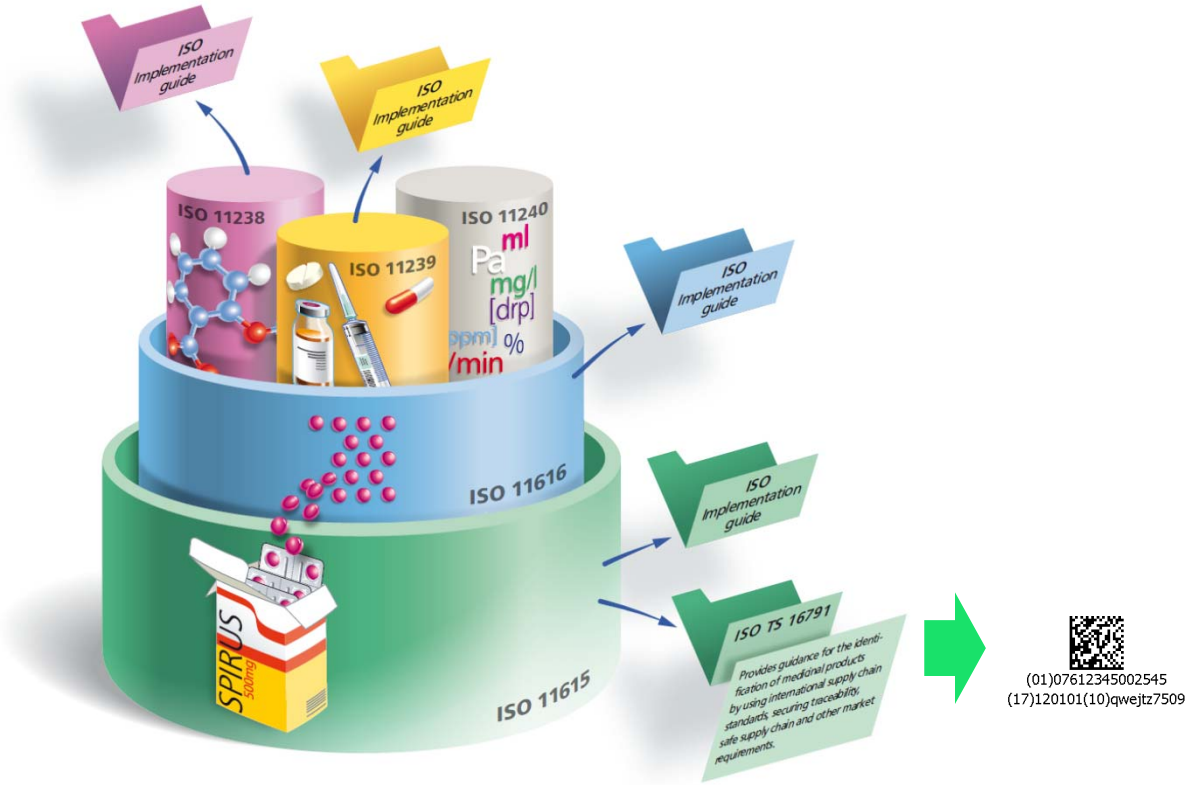
- What is IDMP?
- Why is it important?
- ISO IDMP Global Harmonization
- International Adoption

# What is IDMP?

The Identification of Medicinal Product (IDMP) is a suite of five ISO standards that:

- Defines the data elements and structure to **uniquely** and **unambiguously** identifies medicinal product and substance (regionally or cross regions)
- Creates **common vocabulary** for improved people communication
- Creates **common messaging** standards for improved IT system communication

# What is IDMP?

# Units of Measurement

## ISO 11240 - Data elements and structures for unique identification and exchange of units of measurement

Specifies rules for the usage and coded representation of units of measurement for the purpose of exchanging information about quantitative medicinal product characteristics (e.g.strength)

# Dose Forms & Routs of Administration

ISO 11239 - Data elements and structures for unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation and routes of administration

- Specifies data elements and structure which uniquely and with certainty identify pharmaceutical dose forms, units of presentation and routes of administration related to medicinal product
- Specifies mechanism to associate the translation of a single concepts into multiple languages

# Substance

## ISO 11238 - Data elements and structures for unique identification and exchange of regulated information on substances

Provides an information model to define and identify substance within medicinal products or substances used for medicinal purposes.

- **Substance**: Defined based on its main, general characteristics
- **Specified Substance**: More granular, specific description of a substance

# Pharmaceutical Product ID

## ISO 11616 - Data elements and structures for unique identification and exchange of regulated pharmaceutical product information (PhPID)

- Provides specific levels of information relevant to the identification of a medicinal product or group of (***pharmaceutically equivalent***) medicinal products
- Derived ID based on the following subset of elements:
  - Substance(s)/Specified Substance(s)
  - Strength(s) – Strength units
  - Administrable Dose Form(s)

# Medicinal Product Identification

## ISO 11615 - Data elements and structures for unique identification and exchange of regulated medicinal product information

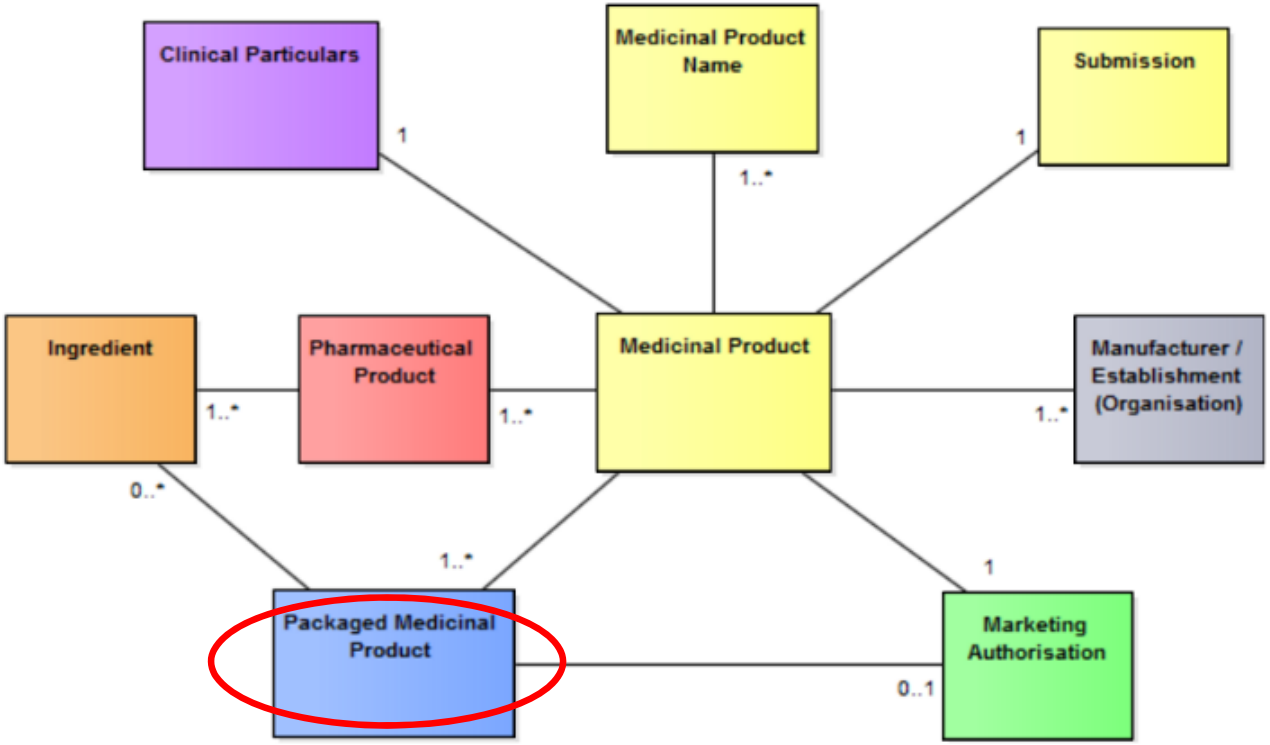
Establishes definitions and concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products.

# Medicinal Product Identification

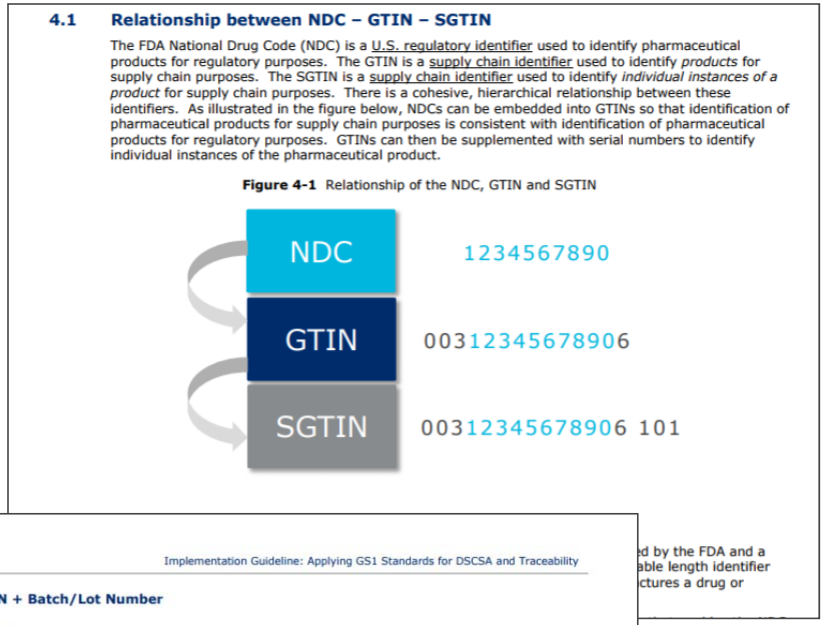
## Primary Identification of Medicinal Products

- **MPID** – Medicinal Product Identifier
  - **Country Code + Marketing Authorization Holder + Product Code**
- **PCID** – Medicinal Product Package Identifier
  - MPID + **Package Description Code** ***NDC***
- **BAID_1** – Medicinal Product Batch Identifier (*Outer Packaging*)
  - PCID + **Batch Number + Expiration Date (ISO 8601 date format)**
- **BAID_2** - Medicinal Product Package Batch Identifier (*Immediate Packaging*)
  - PCID + **Batch Number + Expiration Date (ISO 8601 date format)**

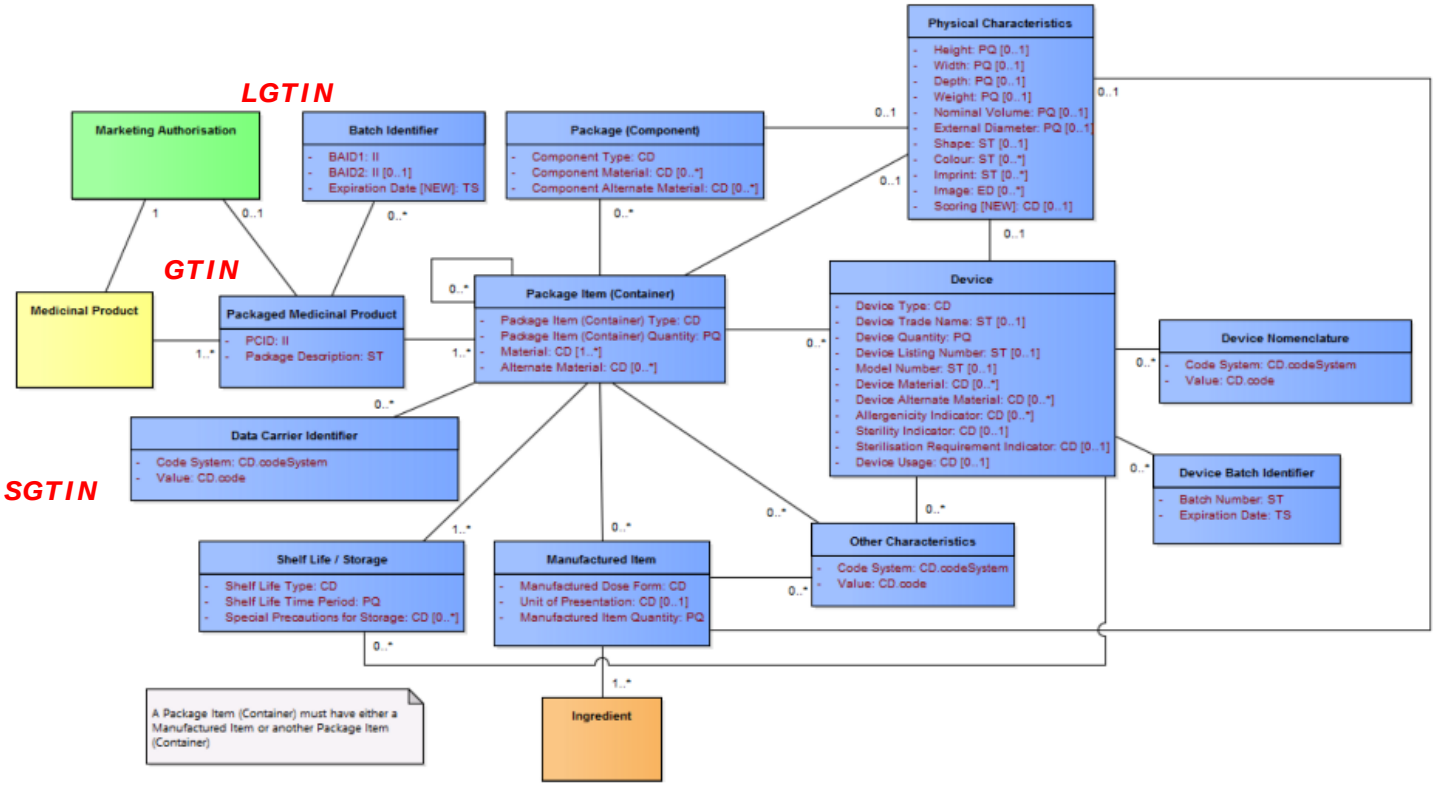
# IDMP Concept Model



# Medicinal Product Identification

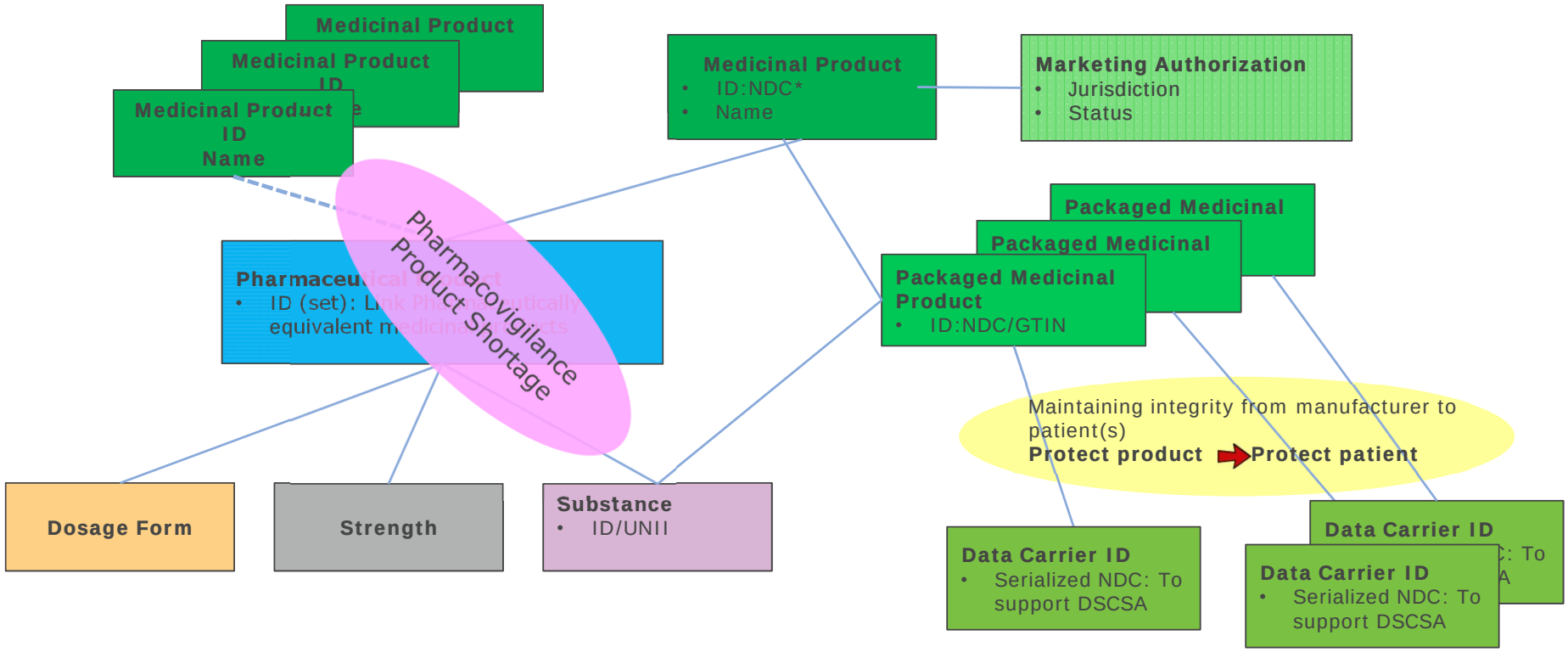

# Packaged Medicinal Product Detail Model



# Why is it important?

- Data standards, like IDMP, creates common language that enables **INTEROPERABILITY**
  - regulator to regulator;
  - pharmaceutical company/clinical trial sponsor to regulator;
  - regulator to worldwide-maintained data sources.
- IDMP can improve **PATIENT SAFETY**
  - Is critical for pharmacovigilance & risk analytics - more specificity leads to more accuracy
  - Helps agencies authorize alternative products when there are shortages
- IDMP can improve **MONITORING OF THE GLOBAL SUPPLY CHAIN**
  - IDMP identifiers will be used to verify packages and batches, screen counterfeits
  - Improves the reporting & tracking of patient safety issues on an international level

# Why is it important?

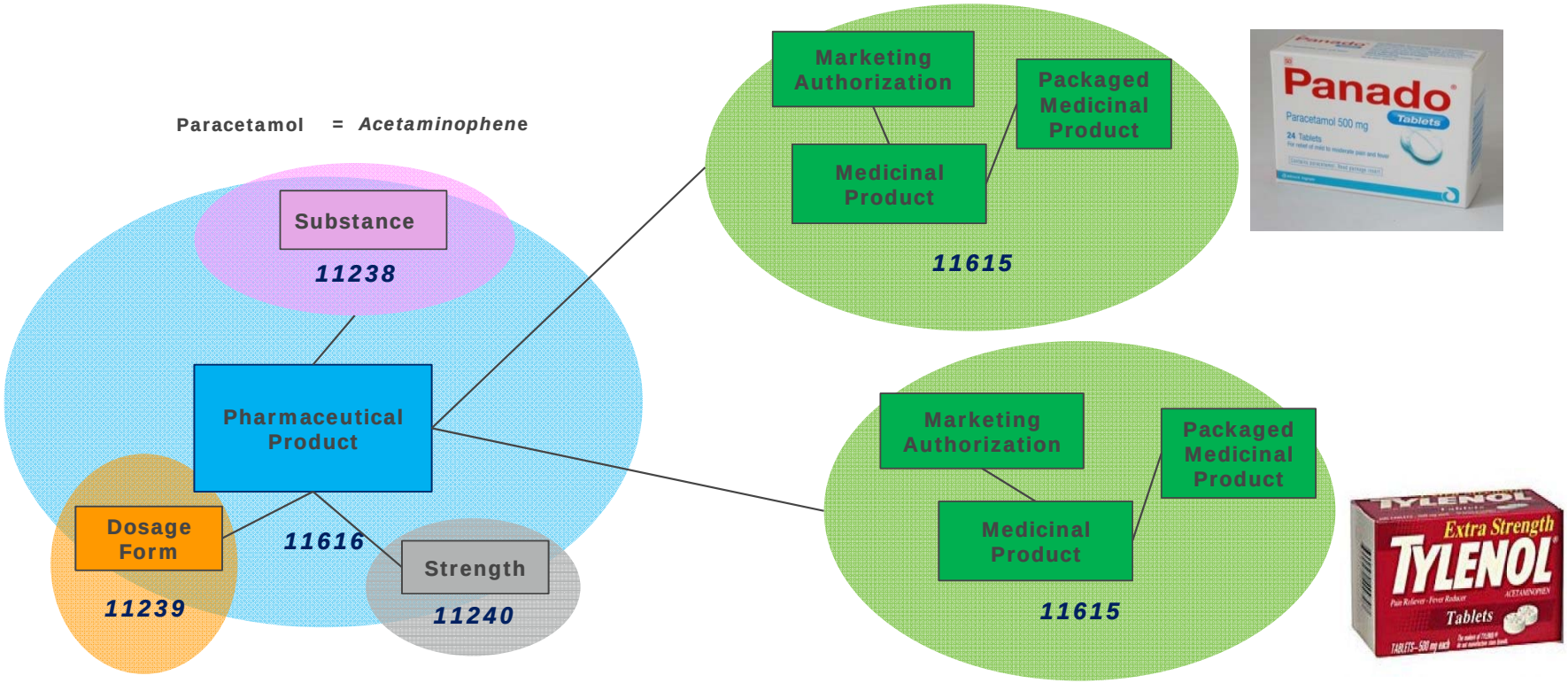


# ISO IDMP Global Harmonization

- Medicinal Product ID (MPID) *Regional Identification (NDC)*
- Pharmaceutical Product ID (PhPID) *(algorithm)*
  - Based on core elements for identification of medicinal products
- Substances
  - Global Substance Registration System *(GSRS)*
- Dosage forms and Routes of Administration
  - European Directorate for the Quality of Medicines *(EDQM)*
- Units of measurement
  - Unified Code for Units of Measure *(UCUM)*

EDQM - The European Directorate for the Quality of Medicines & HealthCare
GSRS - Global Substance Registration System
UCUM - THE UNIFIED CODE FOR UNITS OF MEASURE by Regenstrief Institute

# Pharmaceutically Equivalent Product



# ISO IDMP International Adoption

- EMA/FDA Collaboration
- I.P.R.F. (International Pharmaceutical Regulators Forum)
  - EU, Netherland, Switzerland, Canada, Mexico, US, Brazil, Cuba, Japan, Korea, Malaysia, Singapore, Taiwan, South Africa, Thailand, WHO
- ACSS
  - Australia, Canada, Singapore, and Switzerland
- WHO
  - Can make PhPID adoption easier
- USP

# Discussion Question?  Comments?

# Contact Information

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