# PLS Configuration Strategy

## 1 Introduction

Product, License, Study (PLS) configuration form the backbone of any Argus implementation project. The configuration of PLS may seem a very simple and straight forward exercise but defining the product structure is the most critical aspect. The decision on whether to configure products at strength or indication level versus configuration of product at formulation level has an impact on expedited reporting, aggregate reporting, case processes to post production maintenance hence due diligence is required before finalizing the structure.

A comprehensive PLS configuration strategy is required for documenting the decisions to ensure all critical elements are incorporated in the final PLS structure.

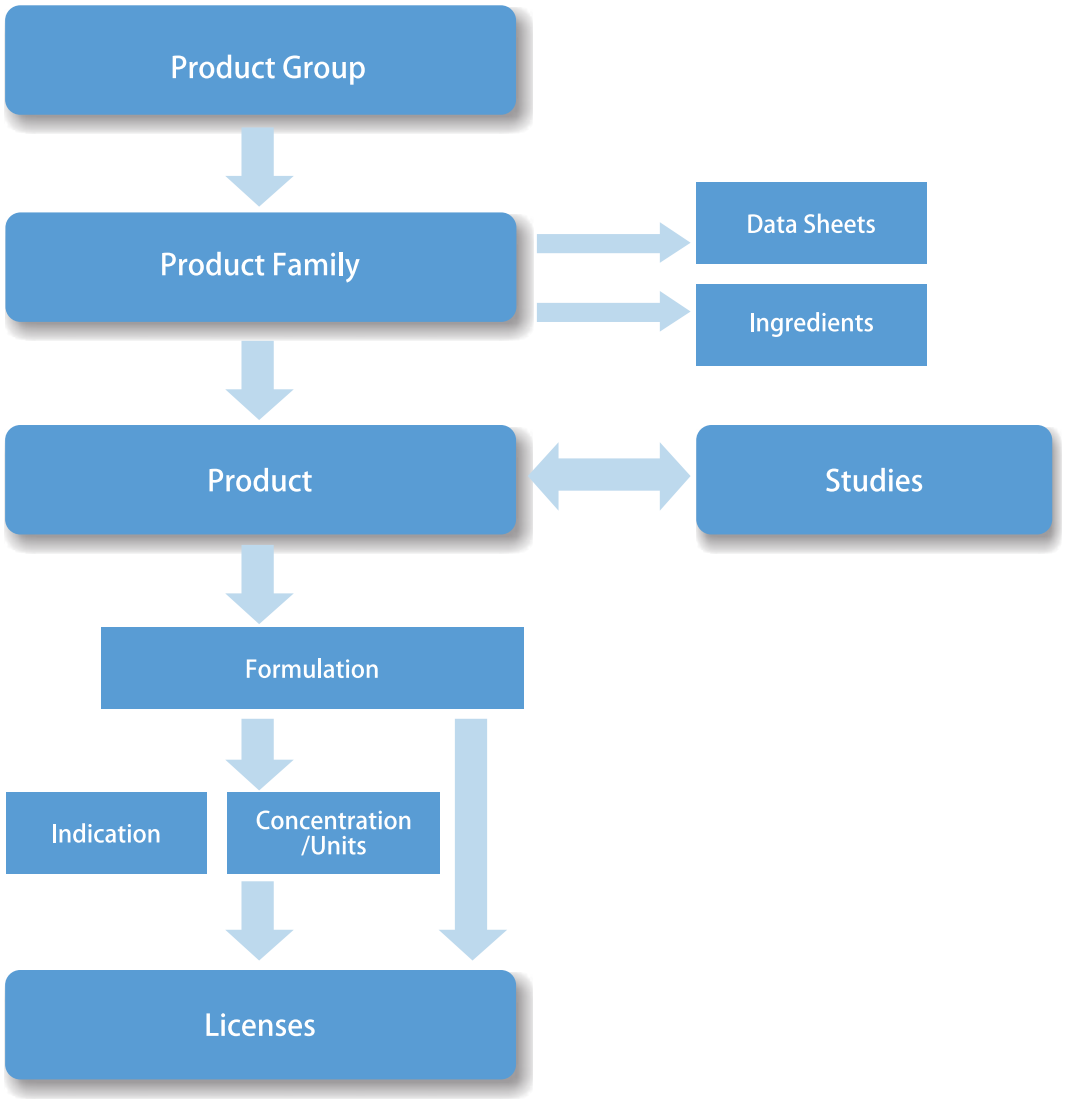


Figure 1 - Product Licenses Studies Structure

# 2 Background

The need for PLS configuration strategy can be explained with help of typical challenges that are faced by organizations while implementing Argus Safety. The challenges could result from harmonizing PLS data between Japan & global safety systems or due to recent product updates that an organization would require to comply with IDMP (ICH M5) standards.

## Challenges in PLS configuration

- US based products
  - Multiple NDAs and INDs per formulation
- Identification of Medicinal Products (IDMP)
- Cross reporting requirements
  - License linking vs Active Moiety functionality in reporting rules
- Harmonization of Japan product with Global product dictionary
  - J Drug Code
  - Clinical Compound Number
- Migration
  - Legacy system data vs future state

Few of these challenges might result in contradictions at product configuration and the standard defined approach would not work in those circumstances. The strategy must ensure coverage of exception scenarios to ensure holistic coverage.

## PLS impact on Safety

Following are few areas that are impacted by PLS configuration:

- Periodic reporting
  - Product formulation v/s strength based
  - License v/s Study based
- Expedited reporting
  - Report output
- Processing of study cases
  - Blinded v/s Unblinded cases
- Business process
  - Case processing work instructions / SOPs

# 3 SOLUTION

There is no single size fits all approach for PLS configuration strategy, a strategy decision valid for one organization might not be relevant for another organization for varied reasons like product portfolio, product approvals and waiver agreements with agencies.

## Guiding principles

One should keep in mind the following for definition of PLS structure strategy:

- Ensure regulatory requirements and reporting obligations are met
- PLS structure shall allow for efficient and accurate case data entry
- Align PLS structure to leverage system's Out-of-box reporting functions as much as possible
- Leverage automated assessment functions of Argus Safety as much as possible

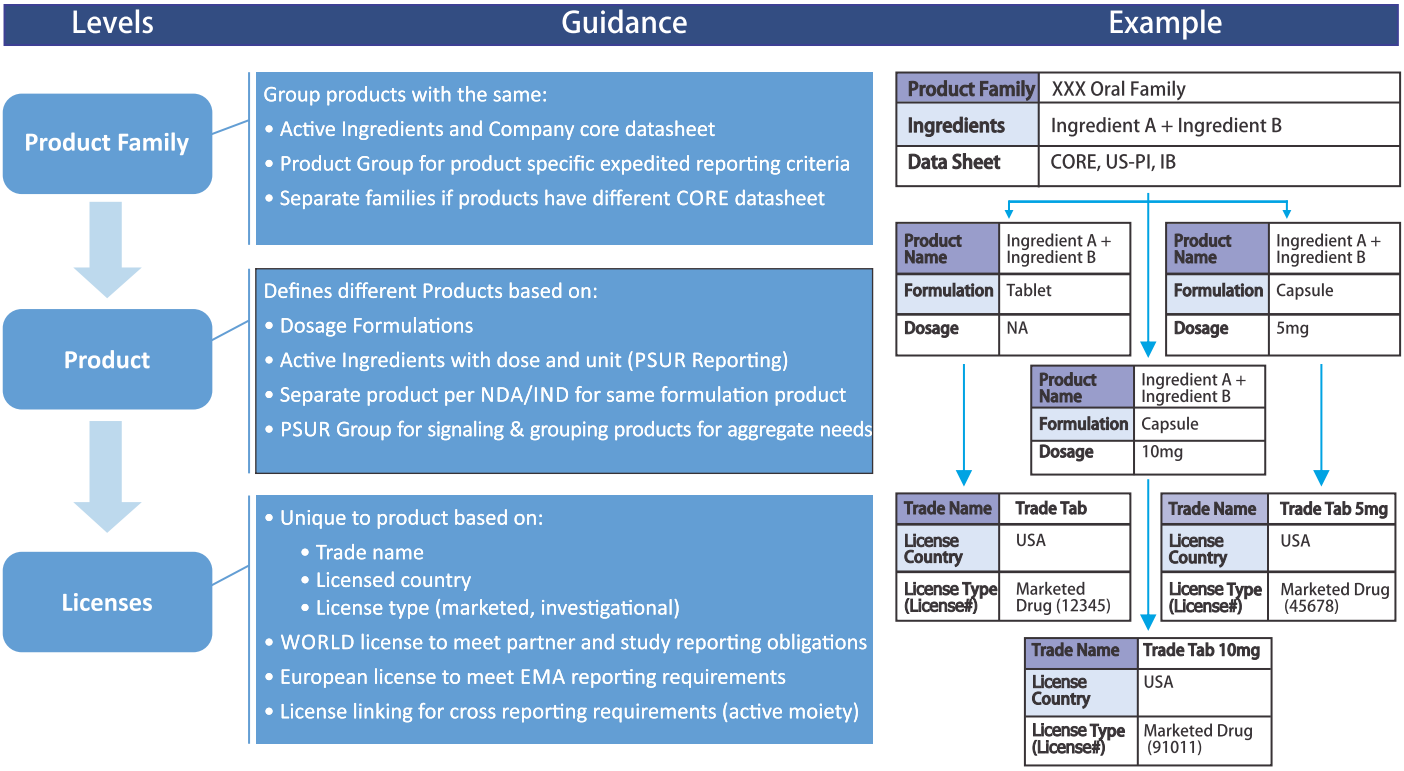


Figure 2 - Product Licenses Structure Guidance

The high level strategy mentioned below is based on experiences from previous implementations at multiple Tier 1 and Tier 2 organizations and are identified as best practices for different elements in PSL configuration.

| Configuration Screen | Best Practice |
|---|---|
| Product Family | Naming convention: Company's Compound Number + Route of administration |
| | Define separate family per CORE datasheet |
| Products | Naming convention: Use generic name of product |
| | Separate products per NDA/IND |
| License | Naming convention: Brand Name / Company code for Investigational |
| | WORLD license to meet Partner & comparator reporting needs |
| Study | Naming convention: Compound ID + "Study" suffix |
| | External comparator products to be configured in Argus |

*Table 1-PLS Best Practices*

It is not necessary to have a defined solution for every challenge but strategy document shall provide directions to deal with the exception scenarios.

In the end the decisions are based on "What is Right" for the organization. The strategy has to be finalized based on understanding of organization's requirements and business processes.

*Please contact us by email (sales@vitrana.com) or phone (+91 120 463 8700) to understand more about how Vitrana™ can help your organization come up with PLS configuration strategy that fits your needs.*