

Global Product Information System

G P I S

Concept & Overview

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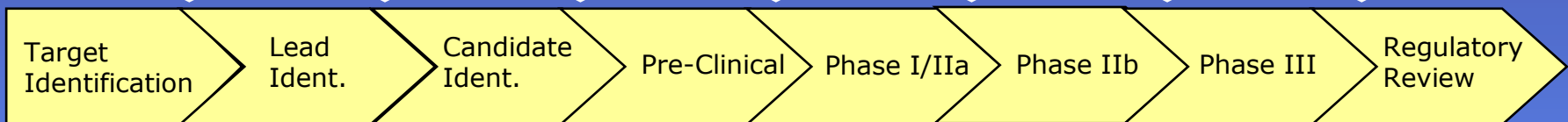
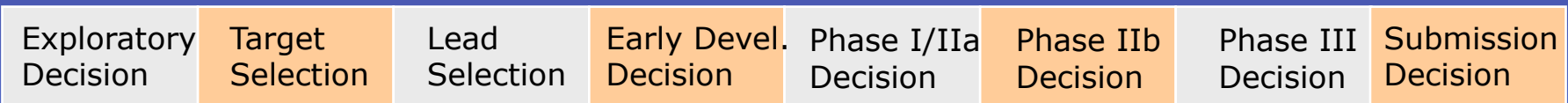


R & D Value Chain

New Products the Source of future Growth

Launch

Decisions

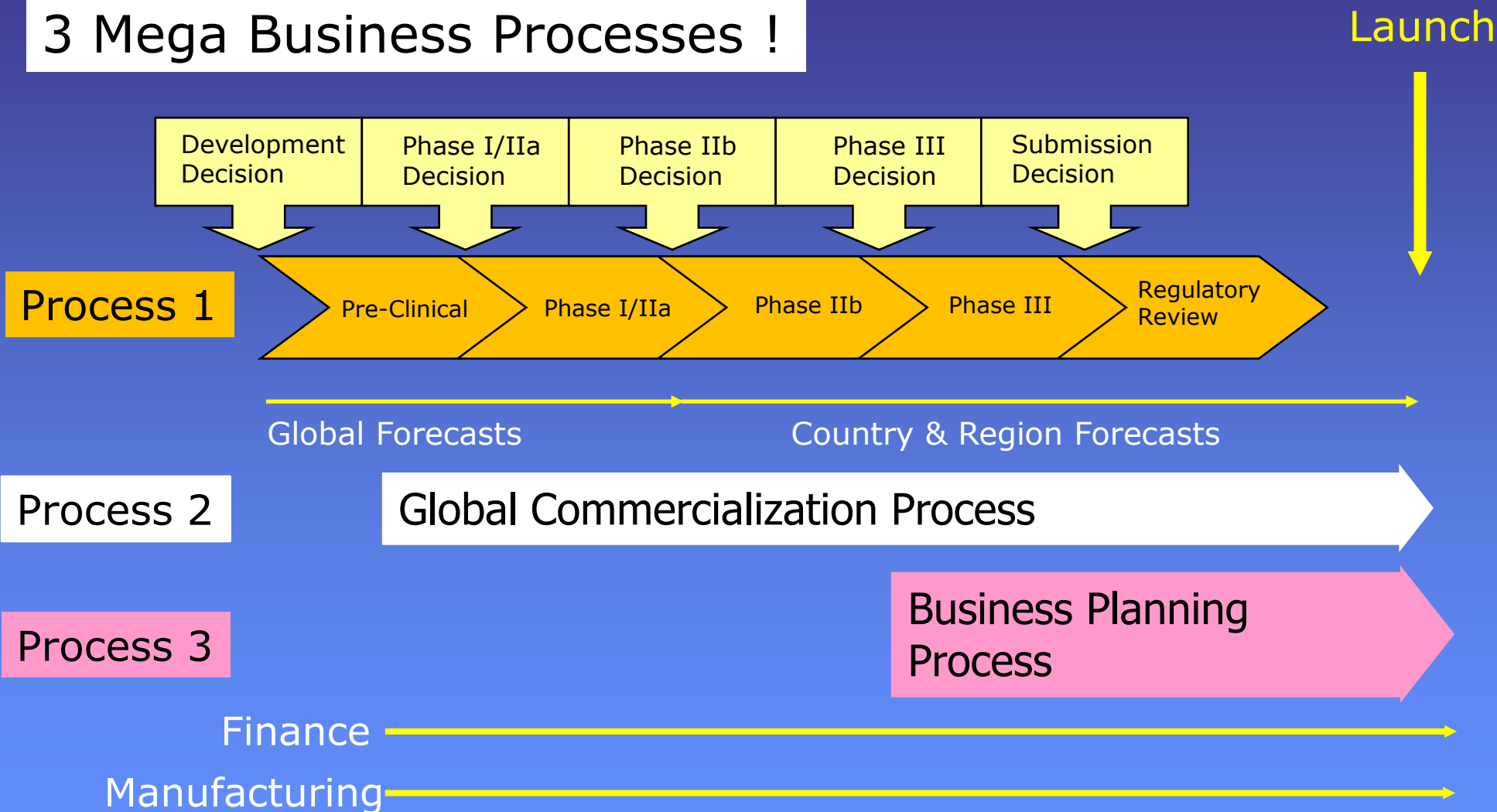


Phases

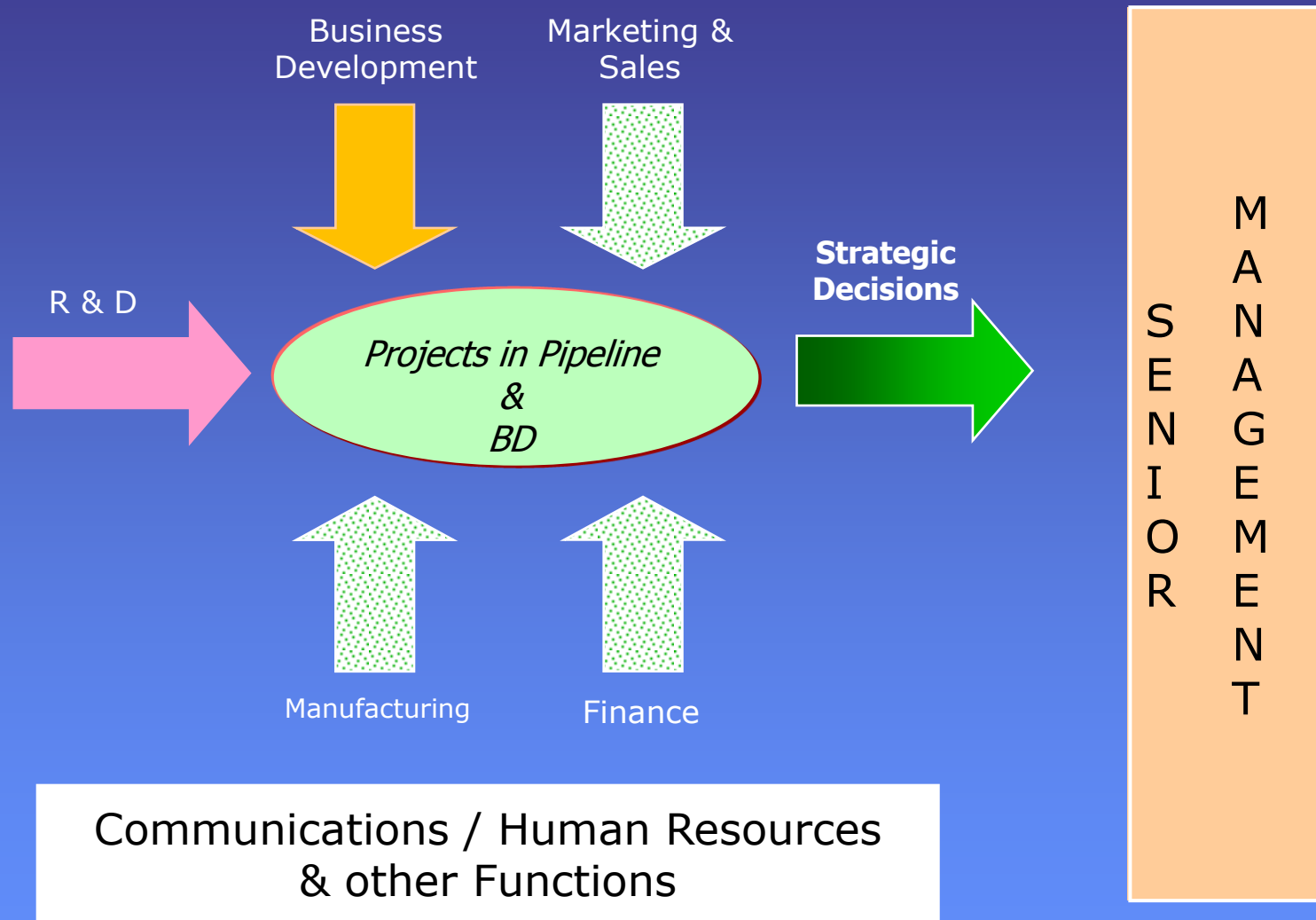


Product Development Process Global Commercialization Process Business Planning Process

3 Mega Business Processes !

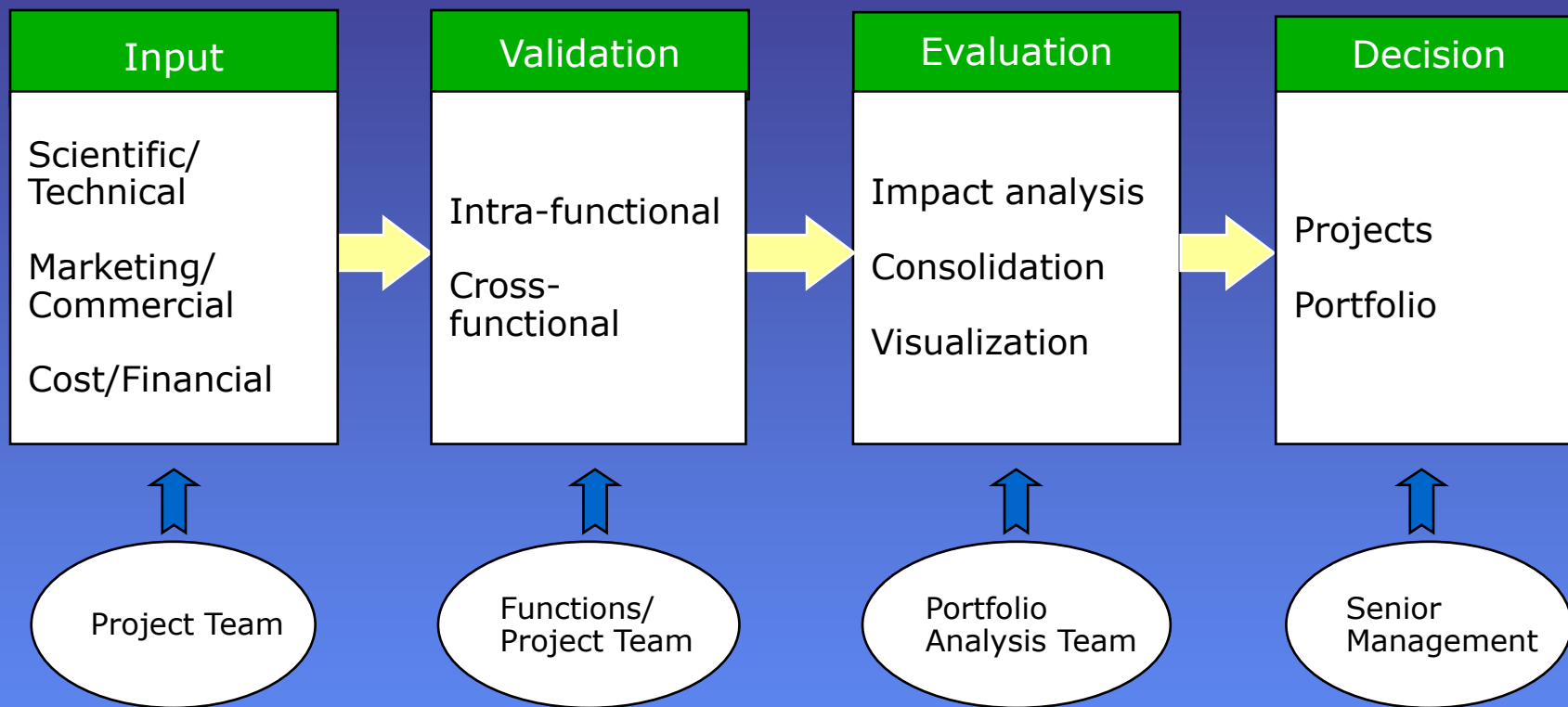


New Product Evaluations Strategic Decision Making Product from R&D and Business Development



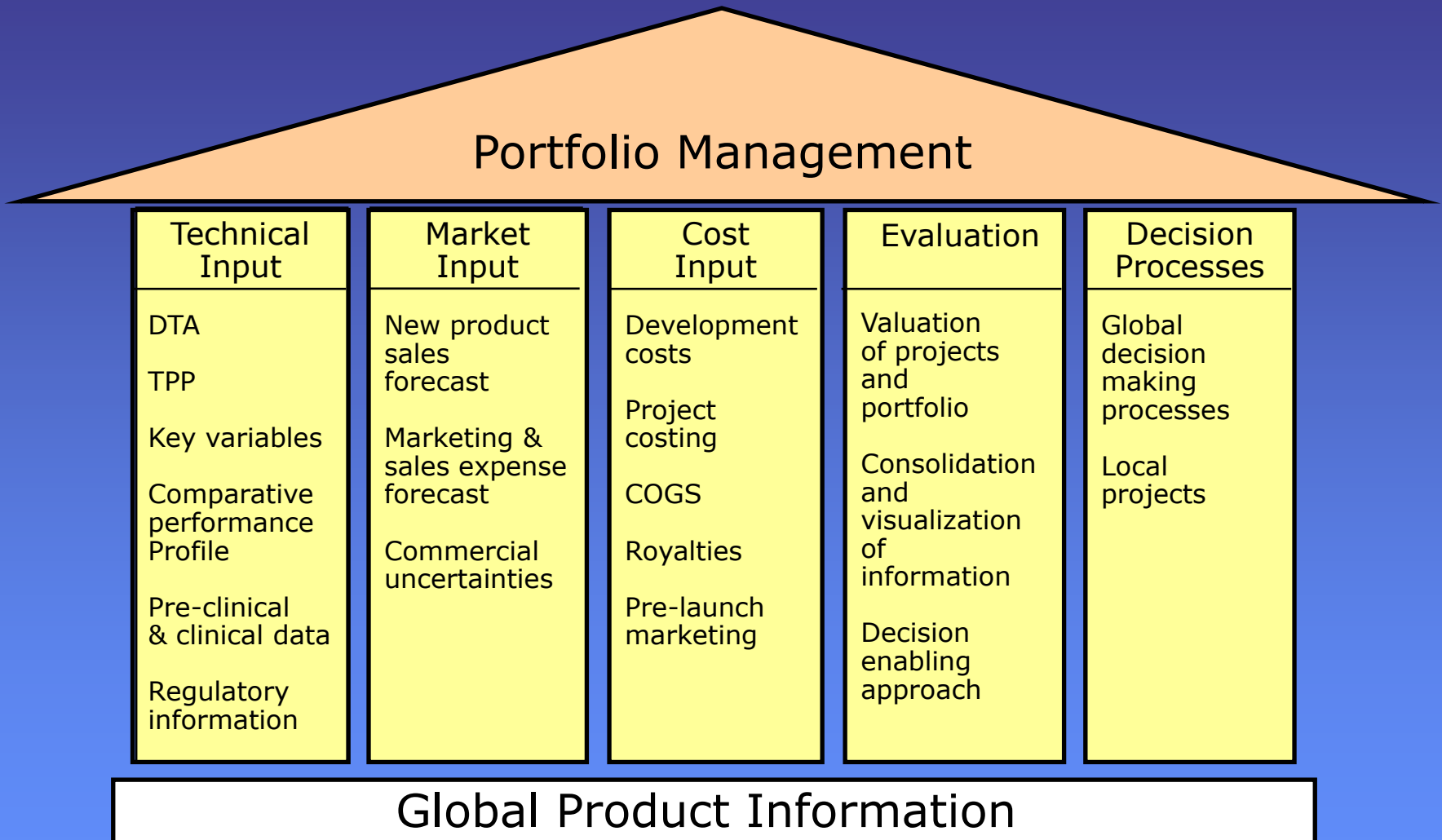
Portfolio Management Process

Cross-functional and pan-geographic Data

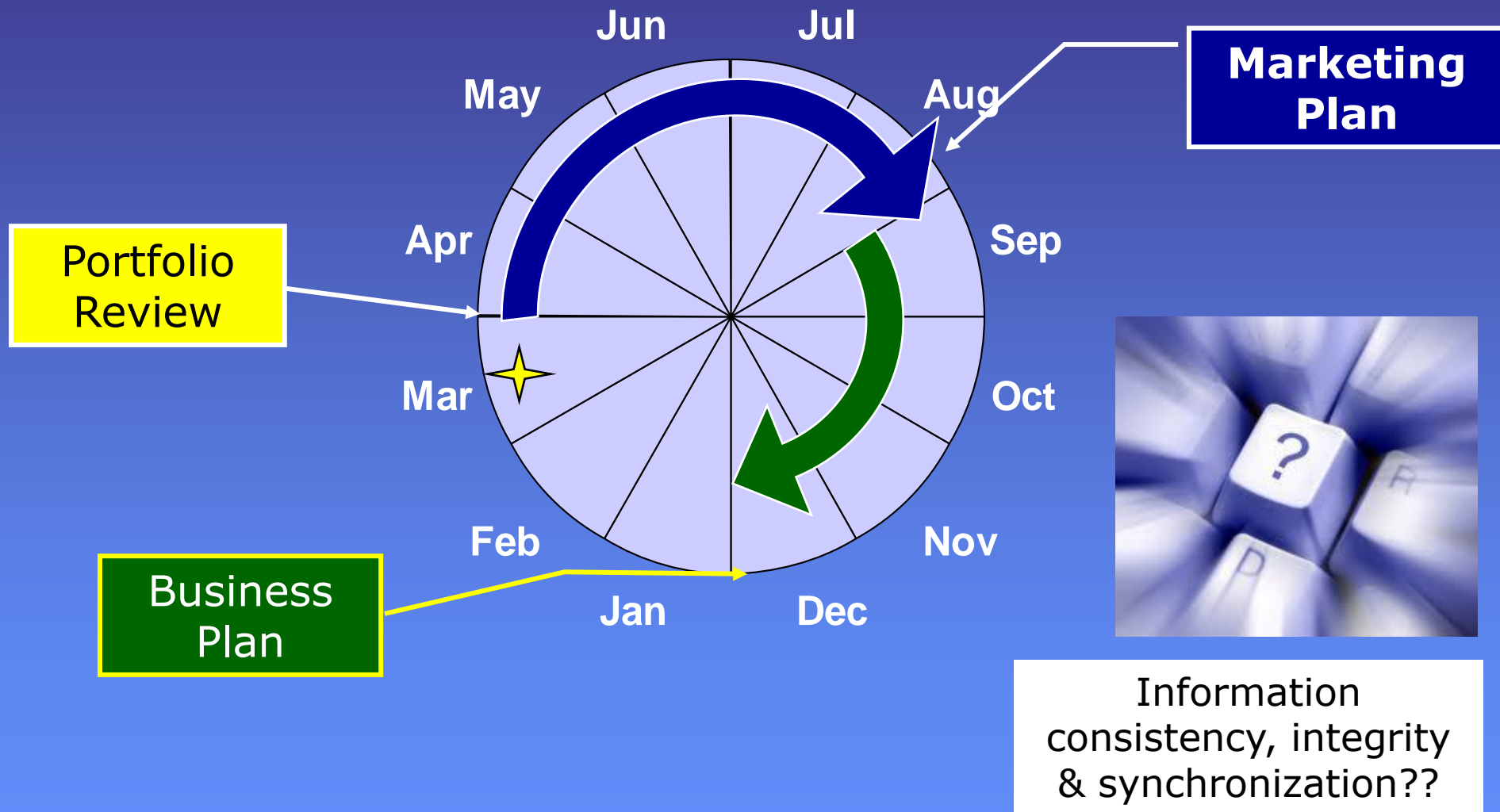


Portfolio Management Process

Global Product Information



Decision Points during the Year 3 Mega Processes with different Time Lines



Information for Decision Making

Cross-functional and pan-geographic

▪ Scientific / medical information

- Pre clinical Pharmacology, mechanism of action, toxicology etc.
- ADME
- Clinical information, efficacy, safety
- Pharmacokinetics, Pharmacodynamics
- Clinical trials design, results TPP, comparators etc.
- Regulatory information incl. Labeling

▪ Commercial Information

- Manufacturing COGs
- Formulation
- Pricing, Reimbursement
- Health economics
- Product Profile (CPP, TPP)
- Market size, patient population
 - Current competition
 - Future competition
- Competitive intensity
- Target audience
- Marketing strategy
- Promotional Mix
- Sales 7 Profit forecasts (P&L)
- Financial data NPV, DCF (risk and non-risk adjusted)

For each decision the cross-functional and pan-geographic information needs to be validated and time-synchronized!



Information Flow is cross-functional and pan-geographic

Potential Inconsistencies

- Development plans
- Overall T & E
- Target Product Profile
- Registration dates
- Reimbursement dates
- Launch Dates
- Competitive assessment
- Pricing assumptions
- Sales Forecasts
- Expense Forecasts



WHY a System?

There are hundreds of data elements that have to be internally and cross-functionally consistent and time synchronized.

Without a system, the chances that the information for decision making is incoherent, inconsistent and not synchronized is huge!



Why a System / Process for Global Product Information?

- Critical information for decision making is Cross-functional, pan-geographic and is scattered throughout the organization
- The same information exists in different “versions” in multiple places in the organization (different updates etc.)
- Critical information is not updated and shared in “REAL TIME”
- Ownership and responsibility for data integrity is not always clearly defined and therefore different “versions” of information are circulating throughout the organization
- Information can be modified without a clear approval process
- Key data (Launch dates, submission dates, clinical trial completion dates) are frequently inconsistent and contradicting each other



Rationale behind a System

- Eliminate inconsistencies and ambiguities by creating a single, cross-functional and pan-geographic information source / system
- Assign and clarify ownership and responsibility for all data regarding Global Projects
- Clarity of Ownership for each data-element
- Clarity of responsibility for data update, validation and approval
- Clear ownership for sales and profit forecasts
- Clear ownership for data generation and approval (data owner)
- Always up-to-date (Real Time)
- New information is shared immediately in “REAL TIME”

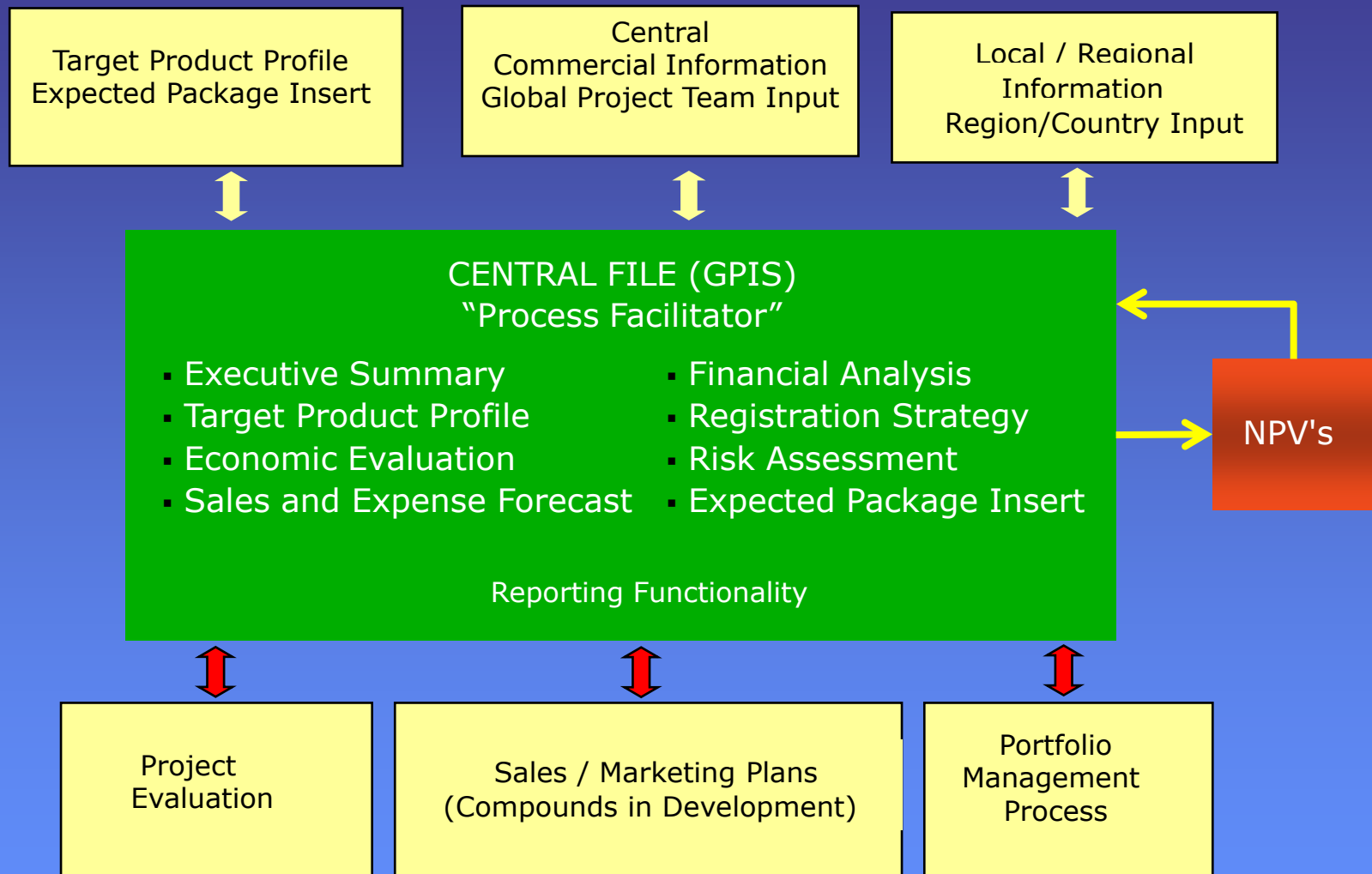


Value of a System / Process

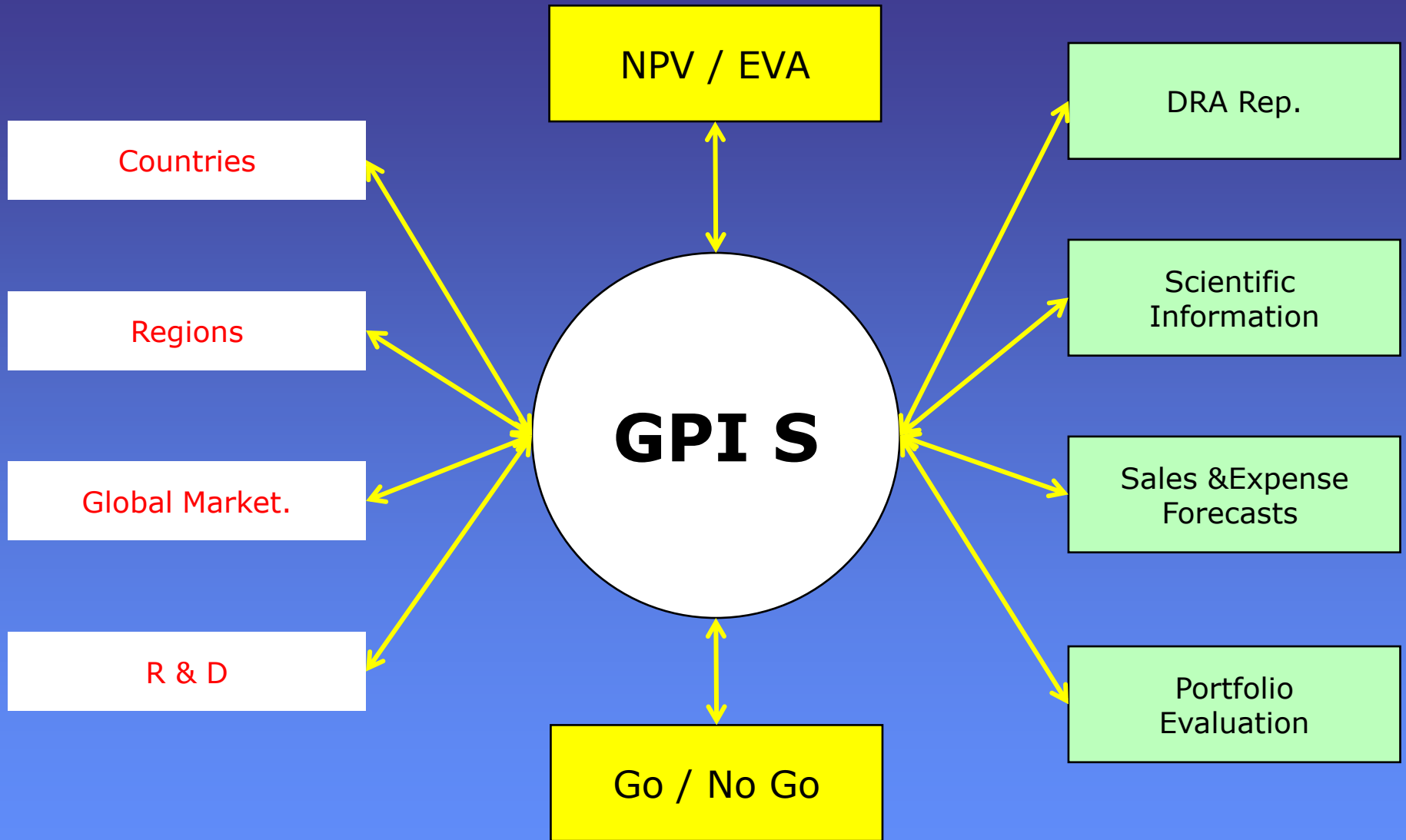
- Summarized high level information for decision making always available in "REAL TIME"
- Cross-functional and pan-geographic consistency of all data
- Everybody involved has access to the same dataset
- Decisions are based on a consistent and validated data
- Clearly defined responsibility and ownership of data
- "No surprises" in the decision making process
- Connectivity and collaboration of all members of project teams and countries
- All projects are evaluated and compared on an "apple to apple basis" (same data set)
- Significant changes can be immediately "flagged" and communicated



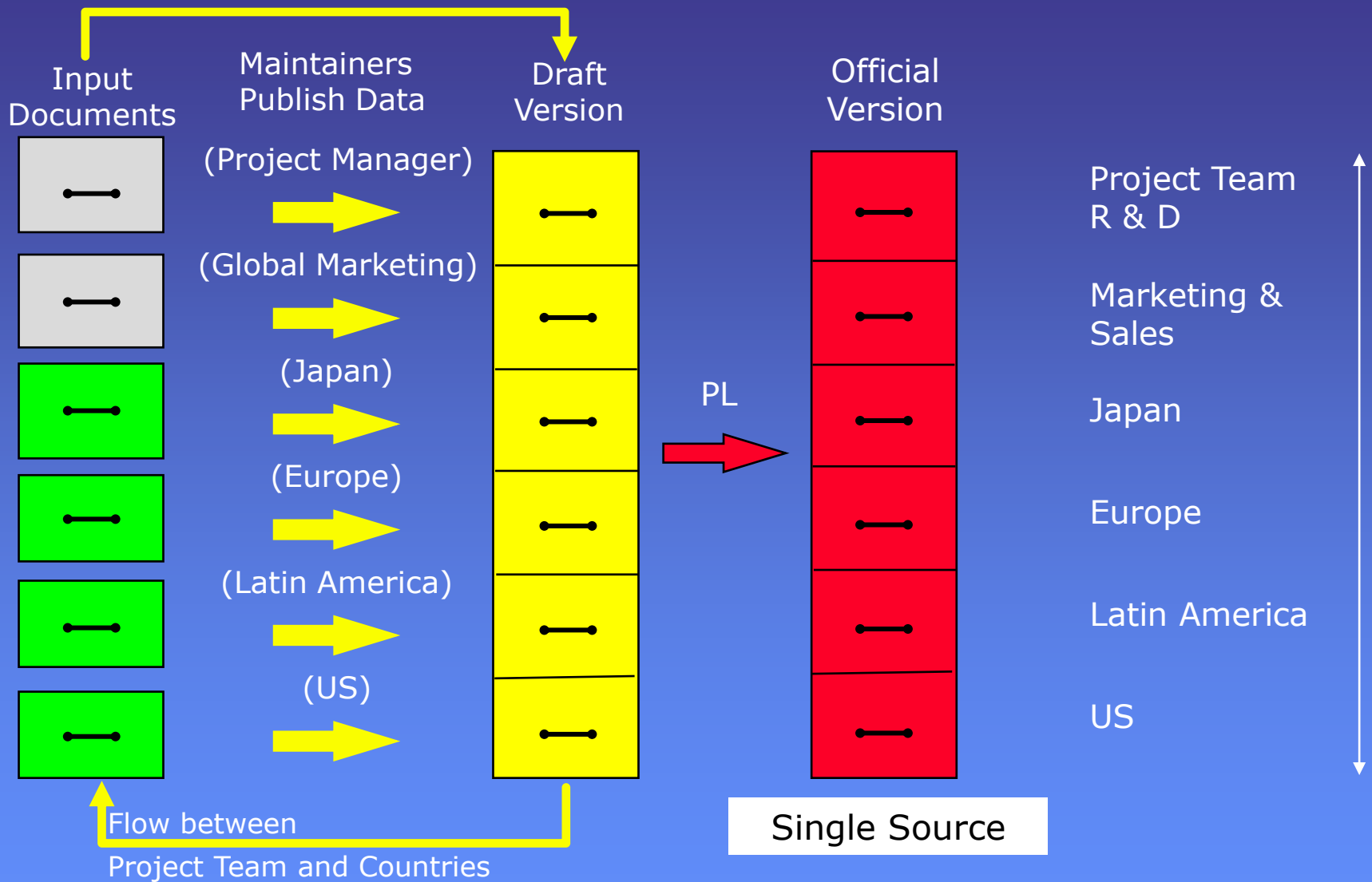
System & Process Overview



GPI S Key Concept



Data Flow in the Global Product Information System



Data Elements

Partial List for Demonstration Purposes

Product Description

- Prod. descript. & Adm.
- Project Team list
- Marketing Team List

Executive Summary

- Risk Assessment
- Expected Package Insert

Medical Marketing Evaluation

- Exec Summary: Global & Cty.
- Med. Mark. Eval. : Global & Cty.
- Product strat. & Sales Forecast:
Global - *Countries*
- Opportunity/Risk Analysis:
Global & Country
- Health Economics Plan - Global

Product Profile

- Chemical Profile
- Pharmaceutical Profile
- Animal
Pharmacological
Profile
- Animal PK Profile
- Toxicological Profile
- Clinical Profile

Development Strategy

- Dev status & schedule
- Summary of clinical
plan
- Co-Development
- Registration strategy
- Economic Evaluation
- Development Costs
- Financial Analysis



Data Owners for Illustration Purposes

Project teams incl. Global Marketing / Commercial Operations:

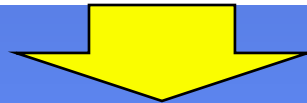
Project leader, Project manager, Marketing / product manager

Clinical manager, Drug Regulatory, Analytics, Pharmaceuticals, Product expert, PK (animal), Drug Safety, Finance

Controller, Health Economics, Medical

Countries :

Brazil, France, Germany, Italy, Japan, UK, Spain, USA



ACCOUNTABILITY = PROJECT LEADER



Roles & Responsibilities for Illustration Purposes

Project Manager

- Inputs Development Status and Schedule.
- Coordinates inputting of scientific information.
- Confirms that scientific information is current and consistent with project objectives. (TPP, Labeling)
- Alerts Marketing and Project Leader of recent updates of project information.

Global Marketing Manager

- Inputs / updates Marketing Executive Summary, Product Strategy, Medical Marketing Evaluation etc.
- Confirms that marketing information is current and consistent.
- Initiates forecasting process; attaches completed model.
- Coordinates updating of Health Economics and Financial Analysis documents
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Official Reports for Illustration only

- Business Case
- Strategic Intent
- Drug Regulatory Approval (DRA) Report
- Global Marketing Strategy Document
- Scientific Summary Review
- Summary of Market Research Findings
- Summary of Clinical Development Plan
- Summary of Labeling Highlights
- Summary of Sales & Profit Forecasts
- Summary of Financial Analysis



Benefits of a Global System / Process

- Clearly assigned ownership and responsibility for each data element
 - Clearly assigned responsibility for updates and approval of changes
 - All changes are communicated immediately in “Real Time”
 - Significant changes are communicated across functions and geographies
 - All projects are compared on an “apple to apple” basis (Same data set)
 - Senior Management has always access to “Real Time” information
 - Changes are immediately accessible for re-forecasting
 - Unified and consistent forecasting methodology
- Clear and transparent decision making process
- Clear and transparent decisions for all projects



Design & Implementation Process

- *I* *imagine*
- *D* *design*
- *E* *experiment*
- *A* *assess*
- *S* *scaling up*

