CONFIDENTIAL
Discussion Paper only

eCTD Move

Life Sciences
Consulting Partners
Competence Center

LSCP *eCTD Move* Initiative

Updated Regulators' Information &

Reconfirmed Strategic 3-Dimensional Thinking

for

LSCP's *Customers & Friends*

Mid 06 eCTD update,

to include DIA Philadelphia Feedback captured

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LSCP Situation Statement & Overview

- **We take it that all Stakeholders have as objectives to contribute to a better and safer health at the lowest cost possible**
- **Accurate/Regulated information shared among Stakeholders is accelerating innovative products to patients**
- **A key contributor for the exchange of information is harmonization in the eCTD format and structure**
- **Comparing the implementation progress over the last 12 months shows that there is "*no way to avoid standardization*" and moving to fully electronic, taking the Change Management (learning curve) into consideration**
- **More and more Agencies are to move to "electronic only"**
- **We would like to emphasize the highest effectiveness will be reached by going the electronic path and only go to paper as needed**
- **We therefore strongly recommend a controlled, but pragmatic approach with a vision and strategy phase giving clear directions for implementation over time!**

In Strategy Process to Review before you start!

- **Our experience and the discussions at DIA Annual 06 for 3 key vision & strategy topics have been confirmed:**

➢ ***VGDS*** **has reached a prominent place:** ***PLD*** **creation!**

➢ **Define** ***Granularity*** **while reviewing all eCTD benefits from the 3-Dimensional perspective, and in consequence**

➢ **Strategize** ***Lifecycle Management*** **(LCM) from the same perspective – not just regulatory! – to**

Reach optimal business benefits with the enabling eCTD Standard

An Additional Topic in IT was the Microsoft Positioning in LS: Ask LSCP to provide MORE Information

FDA Status of eCTD Submissions

as of May 31, 06

- More than 150 Sponsors have registered for the eCTD pilot
- 93 pilot submissions have been received
- Uptake of eCTD is ***increasing dramatically***
  - CDER is exploring withdrawal of eNDA and eNDA guidance

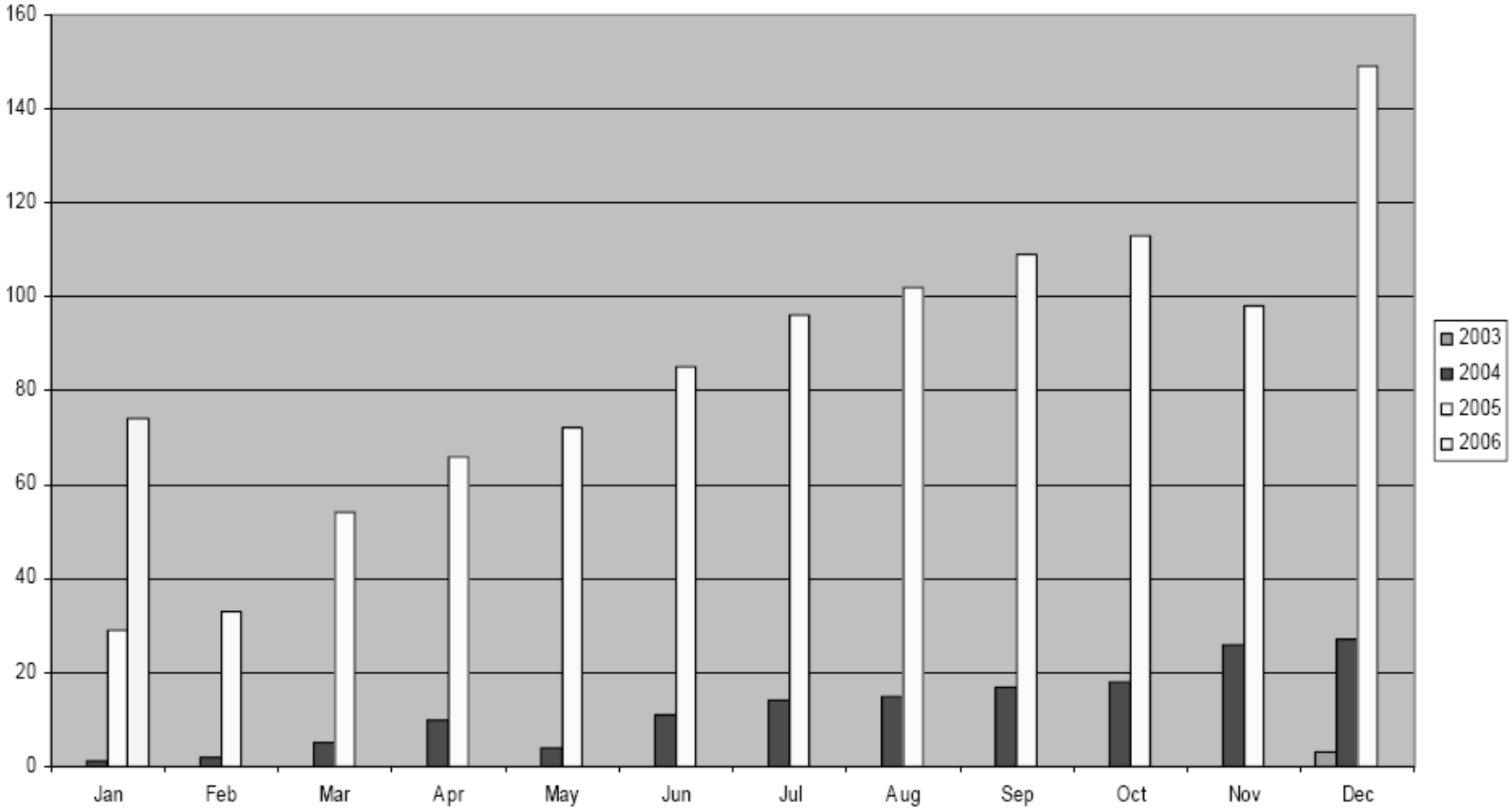
Source: FDA June 06

US eCTD Matrix

Application Type	# of Applications	Submissions
Master File	14	17
IND	119	1,312
NDA	71	1,194
ANDA	72	236
BLA	18	599
Total	**285**	**3,358**

Source: FDA June 06

Growth of eCTD by Month



Source: FDA June 06

What is FDA Doing?

- Implemented 2nd Generation Review Tool in June of 2005
- Published Final eCTD Guidance in October 2005
- Making its resources available to Industry through groups like DIA, RAPS, GPhA
- Providing resources during pre-IND and pre-NDA/pre-BLA meeting through Regulatory Review Support Staff

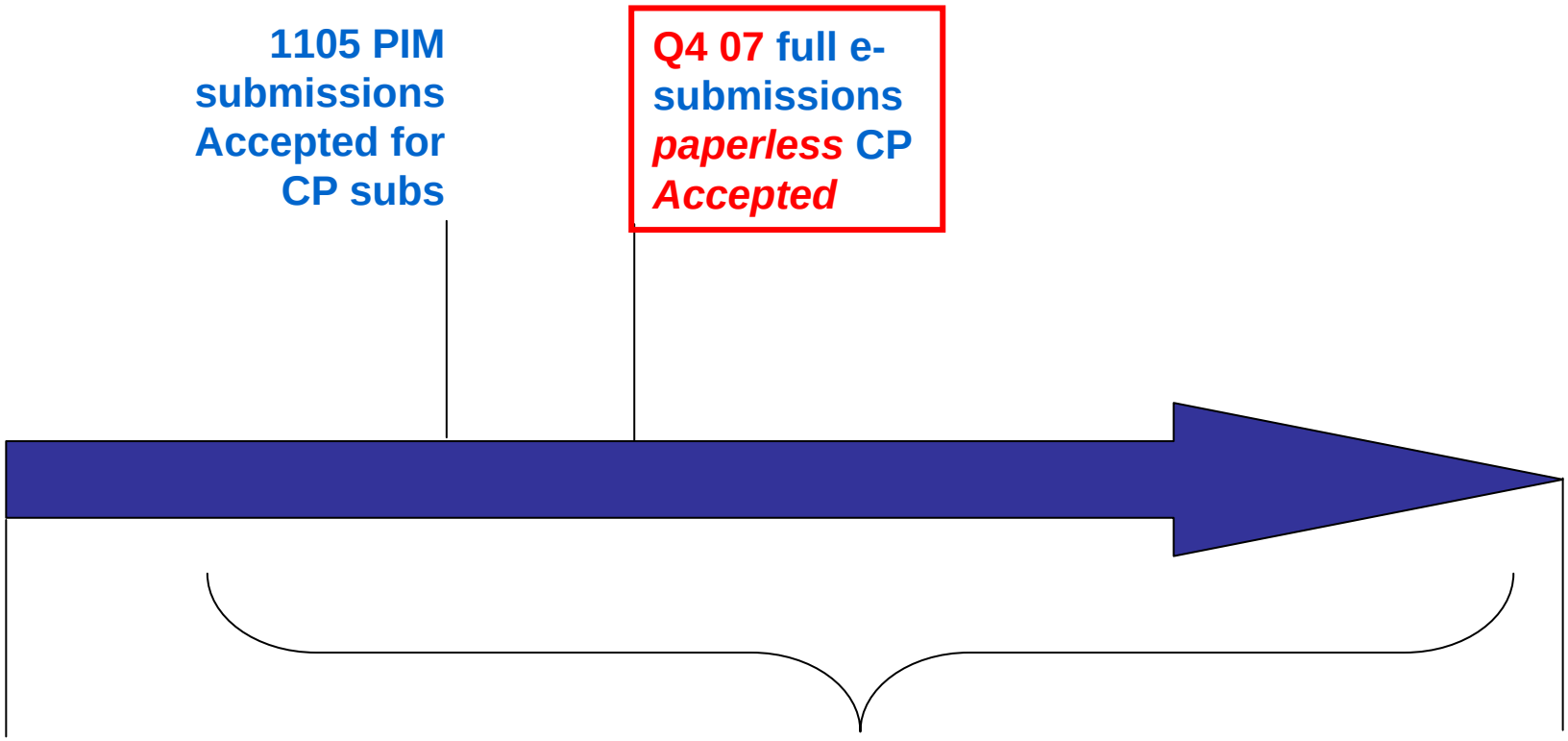
Source: FDA June 06

… Beyond eCTD

- FDA Is becoming a standards based organization
  - Partnering with HL7, CDISC, and others
- Current Standards
  - Structured Product Labeling
  - Study Data Tabulation Model
  - Standard for Exchange of Nonclinical Data

Source: FDA June 06

EMEA eCTD Timeline Summary:
European Union Review System (EURS) Project



Slide reproduced by LSCP from DIA EMEA Presentation

EMEA: Use of eCTD to Paper …

EUROPEAN UNION - NTA volume 2B: Practical Guidance for the Paper Submission of Regulatory Information in Support of a Marketing Authorisation Application when using the Electronic Common Technical Document (eCTD) as the Source Submission, V1.0, Feb-2006

Current version. This document replaces the Practical Guidance for the Paper Submission of Regulatory Information in Support of a Marketing Authorisation Application when using the Electronic Common Technical Document (eCTD) as the Source Submission, EMEA/C/6148/04, v 0.3, 09-Jun-2004 (47446) The goals of this guidance are to enhance the ease of receipt, processing and review of eCTD submissions and associated paper submissions at the EMEA or National Competent Authorities and to ensure efficient submission handling. Specifically, this guidance makes recommendations regarding the presentation of the paper submission that is provided by the applicant when an eCTD submission is also provided and acts as the 'source' submission for all hard copies.

Implementation Objectives

- By the 2009 deadline the European Regulatory Network will have the infrastructure and processes in place to handle electronic submissions to successfully support the related decision-making processes for medicinal products within the European Union.

- Full adoption of the eCTD is defined as:
  - No requirement for any accompanying paper submission or paper archive copies
  - Valid for *all* European procedures (Centralised Procedure, Decentralised / Mutual Recognition Procedure, National Procedures); and,
  - Valid for *all* types of submissions (Marketing Authorisation applications and renewals, Type I and Type II Variations, Responses to the LoQ, other MA related Follow-Up Measures)

- Does not imply that the electronic submission of a new dossier will be mandatory by 2009.

Source: EMEA June 06

eCTD Implementation for EMEA

- What does successful 'implementation of eCTD' entail for EMEA?
  - The eCTD is accepted as a 'common currency' for product marketing authorisation applications.
  - Electronic-only submissions are accepted
  - The use of the eCTD at the EMEA is supported by appropriate SOPs for receipt, validation, storage etc
  - The use of the eCTD at the EMEA is supported by appropriate business processes

Source: EMEA June 06

Wider EU Implementation

- *At least* 3 Member States (Belgium, The Netherlands, UK) have implemented electronic only submissions in 2005; some even considering eCTD-only implementation from 2007 – (important differentiation)
- EMEA has agreed to work towards acceptance of electronic only submissions by Q4 2007

Source: EMEA June 06

… and Japan

JAPAN –

PMDA Notification No. 0629005: Handling of Electronic Common Technical Documents (eCTD), 29-Jun-2005

This document presents the following points to note when submitting data accompanying approval applications on eCTD to the Pharmaceuticals and Medical Devices Agency (PMDA). The contents include the eCTD submission procedure, the eCTD creation, and Checklist for the Electronic Common Technical Document Specification (ver. 1.2).

… with eCTD accepted, but Paper still "original" (some Modules require Japanese translations (M1; 2; 5), as of June 22, 06

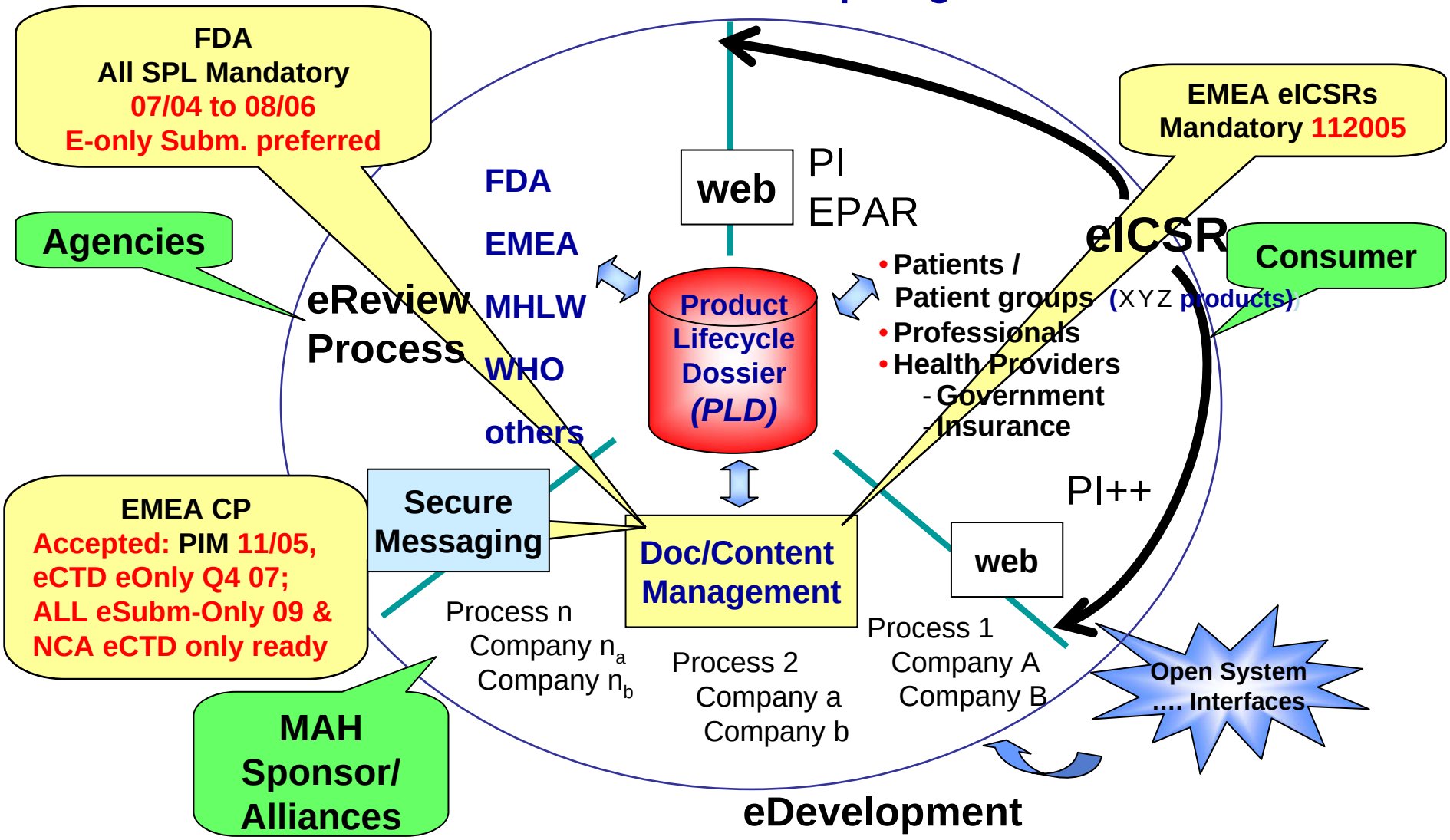
CHINA - SFDA Notification No.[2006]202

Notification: Promulgating Guidance for Patient Information Standard of Chemical Drugs and Biological Products, 10 May, 2006 (English/Chinese version)

This Notification is ***drafted to uniform the patient information*** standard in China, containing the patient information form and writing requirements for each article. It concerns the chemical drugs, the therapeutic and preventable biological products.

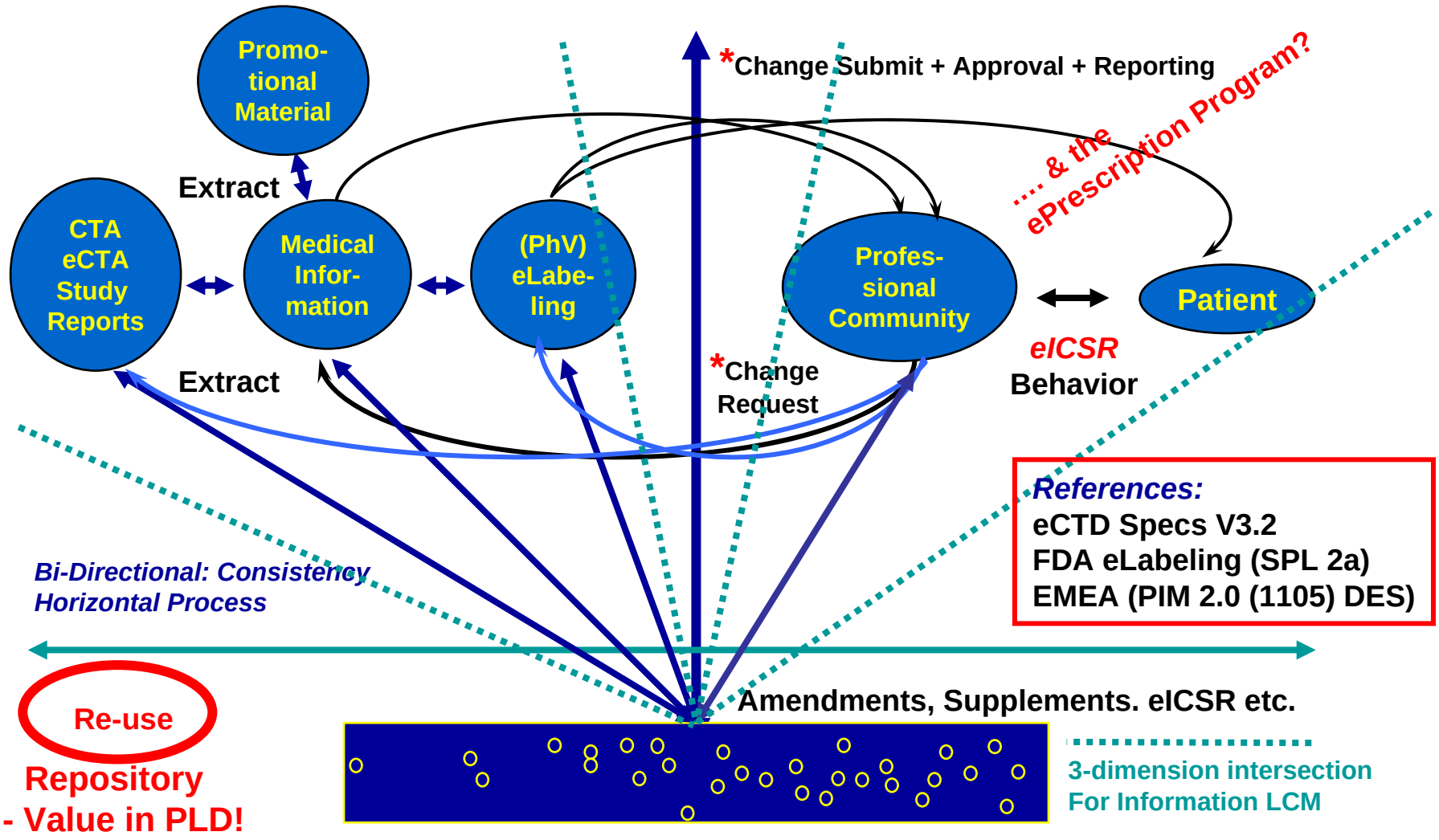
The Holistic Harmonization Horizon & Status:

One "Transparent" Process - eCTD enabled. This new environment will create/adapt regulations!



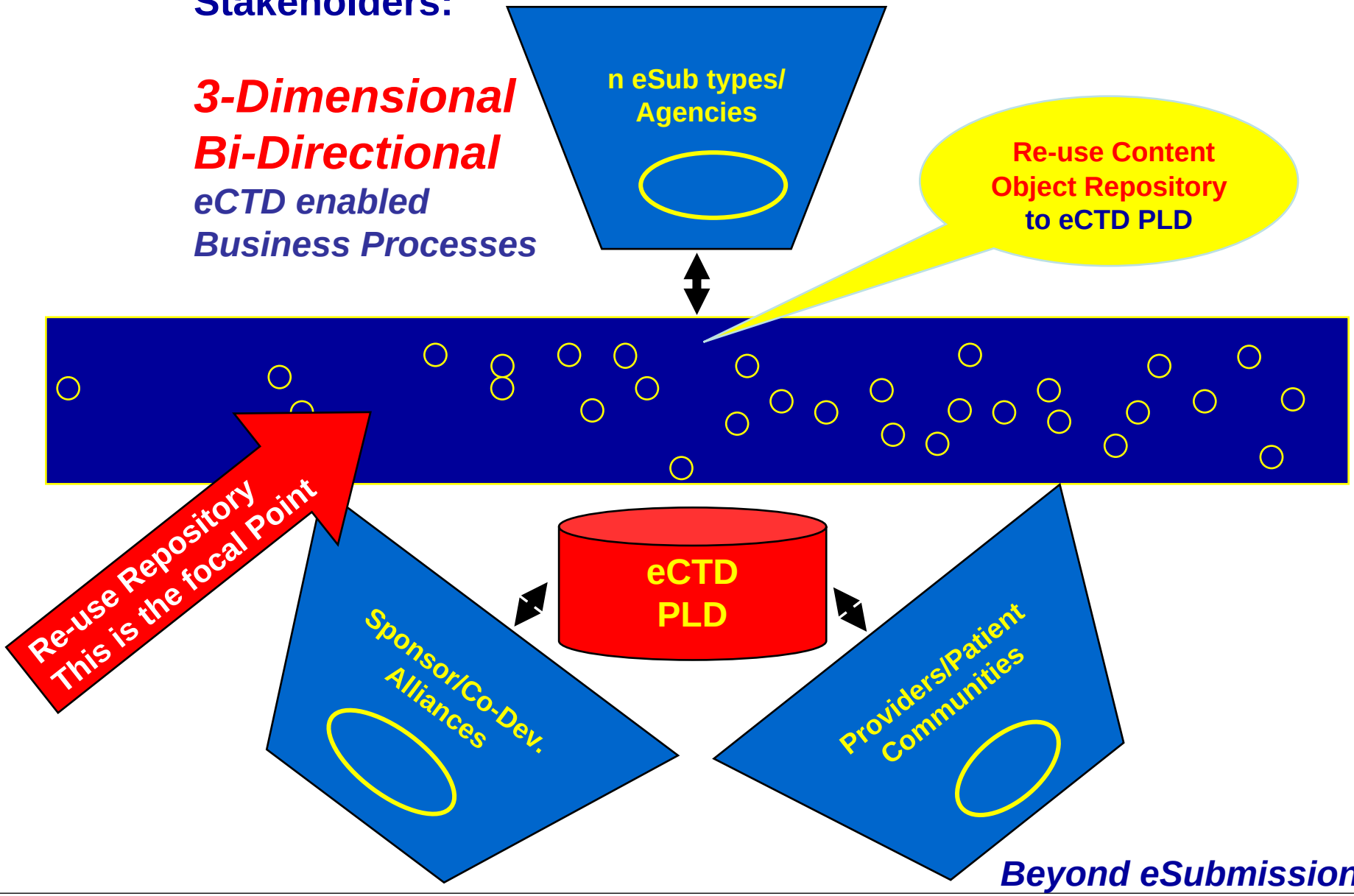
Example: eLabeling Business Process
- *eCTD Perspective*

eLabeling Submission: Agency Approval, including Changes



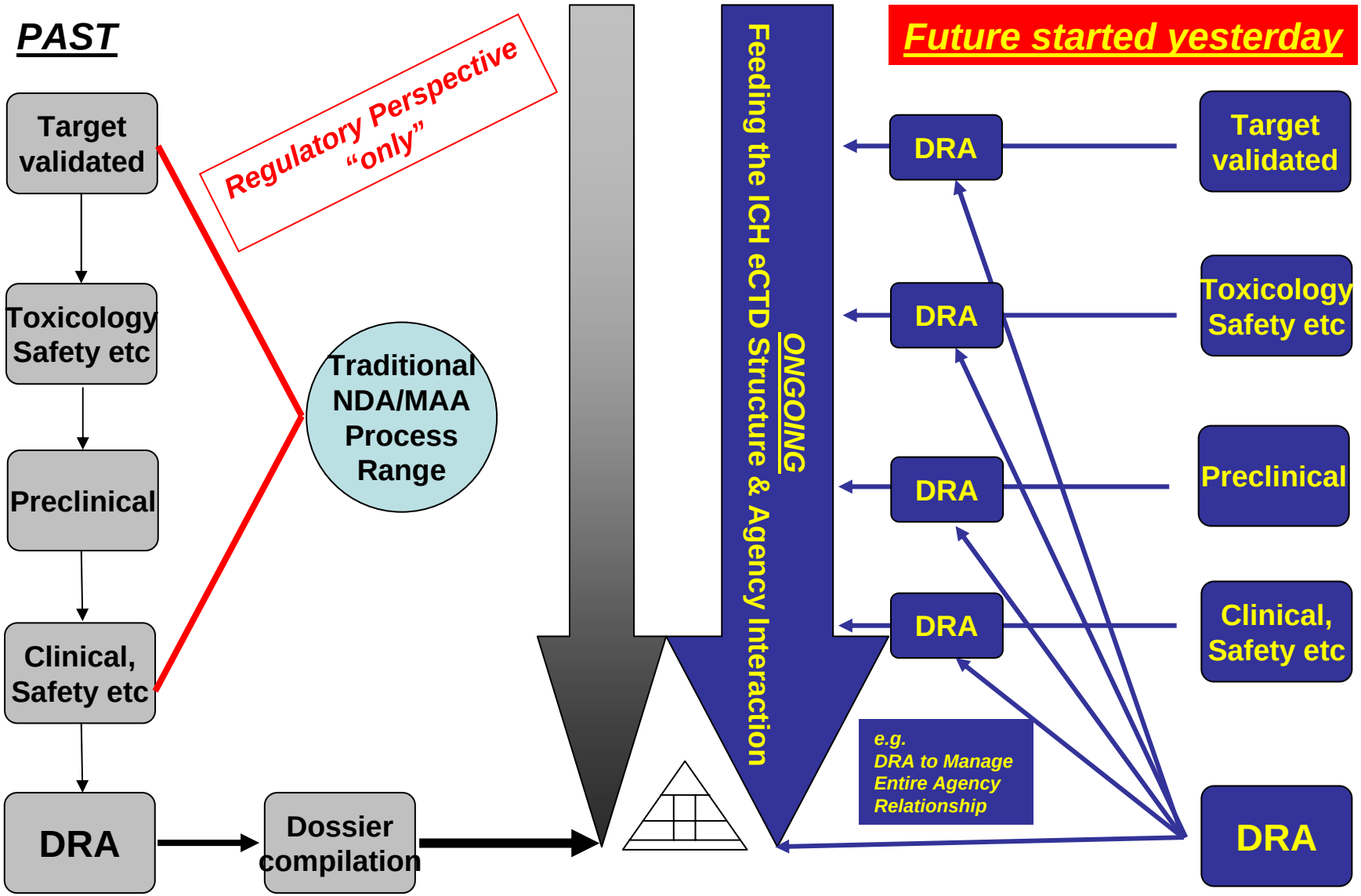
Getting Controlled, Transparent Content Flow to All Stakeholders:

3-Dimensional
Bi-Directional
eCTD enabled
Business Processes



Beyond eSubmissions!

Different Processes/Organization: E.g. "Rolling Submission" *DRA to Manage Entire Agency Relationship*



Vision & Strategy getting started: The Program Plan & Path to …

Kick-off eCTD Business Framework

Moving from Managing Document/Content to Managing Products and Beyond

Define **Phase 1**	***Apply*** **Phase 2**	***Execute*** **Phase 3**	***Maintain*** **Phase 4**
Vision/Strategy eCTD Priorities Identified, Process and System	"Layered" Content PoC Pilot Application & Infrastructure	Content/eCTD/ Rolling Submissions eCompliance Business Model	Product Lifecycle Management to Product Lifecycle Dossier

Recognize High Value Opportunities

Reduce Cost of Operations

… Manage Risk

Adapt Frequently Maintain Agility

Long term strategy:
Reach lowest Total cost of Ownership!

Today's Conclusion:

The Confirmed Correct Perception:

"eCTD is Primarily a Business enabling and *not* a Technology Standard!"

- **The path to maturity of eCTD Stakeholders and to implement becomes manifest**
- **Enterprise Transformation Challenges become visible**
- **Looking at the timelines: There is still Momentum to move away from point solutions that appear to be under regulatory pressure and have a view of the broader scope**
- ***Time to re-think*: Let us stick our heads together, talk and look at a pragmatic approach,**

  e.g.

  ***Rolling & Collaborative eCTD Submission management* … !**