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Evaluating a Modular Solution for Enterprise Regulatory Information Management

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Spotlight Topics

- Analysing the decision between single and multiple tool solutions
- Challenges faced by suite implementation
- Overcoming the challenges of different tools effectively communicating together
- Lessons and advice to industry peers for RIM solution implementation

Single vs. Multi-vendor/Modular Solutions



VS.



iPad vs. PC – from integration perspective

An iPad integrates:

- Computer
- Camera
- GPS
- Phone network (3G/4G)
- iPhone has all above and a phone feature



A PC integrates:

- CPU
- Monitor
- Mouse
- Keyboard
- Printer
- Audio/speakers
- USB drives/devices
- ...



iPad vs. PC – from an architect's perspective

- iPads are designed primarily to be a closed, all-in-one system
- PCs are designed with an open system architecture in mind and allow multiple vendors' devices to work together
- How much does it cost to
 - Upgrade a 16GB iPad to a 64GB iPad?
 - Add 3G/4G capability to an iPad?
 - You can't unless you buy a new one
- PCs are better designed than iPads. Yes?

Challenges, Risks and costs with single vendor solution

- **Putting all eggs in one basket**
 - Even “market leaders” can struggle or disappear
 - e.g. RIM Blackberry, Nokia, Yahoo, ISI, ...
- **Opportunity Costs**
 - Niche players specialize in their niches and can provide best solutions in their specialized areas
- **Cost of upgrade or exit**
 - Vendor lock-in, costly customizations and upgrades
 - Data Migration (if it’s even possible) upon exit

Challenges of Multi-vendor Solutions

- Integration not likely to happen without open, common interfaces and standards
 - SQL, DQL, API, Web Services,..etc
- Integrations may require hard-wired logic and coding
- If there is a problem, which vendor is the first point of contact and who to decide who is at fault?

Overcoming the Challenges of Multi-vendor Solution

- Design your enterprise information exchange architecture and standardize interfaces independently from vendor tools
- Leverage open standards and demand software vendors' compliance with the standards
- Select vendors and tools that have track record and known to be standard-compliant

How do you cross a muddy road?

Buy an SUV

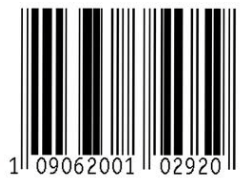


Build a Monster



An Alternative – Build the Infrastructure





Leveraging Standards



- Standards make the world runs more efficiently and integrated
 - Barcodes
 - The Universal Serial Bus (USB)
 - API, Web Services
 - eCTD, EVMPD
- Short-term pain but long-term gain

Standards for Life sciences & Healthcare Industries

- Standards for life sciences and healthcare
 - MedDRA/WHO-ART
 - HL7, eCTD, RPS
 - EVMPD/IDMP
- No standards for internal communications among RIM systems
 - How do you communicate the event that a new compound gets its INN?
 - How do you communicate the event that a market authorization application is approved among RIM systems?
 - How do you propagate a litigation/legal hold event to RIM systems through out the enterprise?

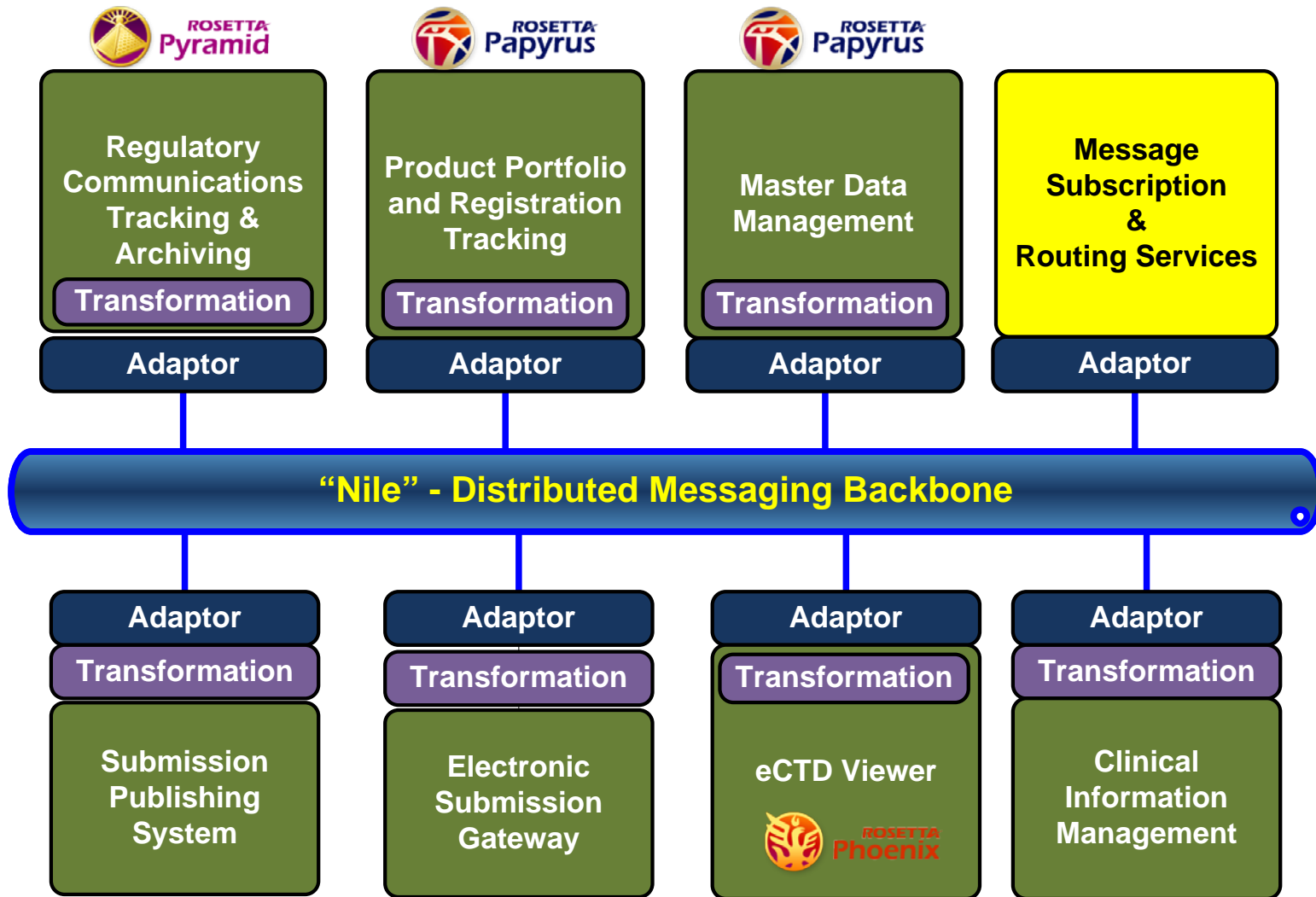
Introducing ROSETTA Nile™

- Identify and standardize common data types, artifacts and events that are necessary for regulatory Information exchange
- Define (de facto) messaging standards and communications protocols for event propagation (including data exchange) among RIM systems.
- Build a central message processing and routing services that guarantee the delivery of messages to information subscribers
- Loosely coupled design enable systems to be plugged in or unplugged without affecting other participating systems in the enterprise (like PC components)

Components of a PC

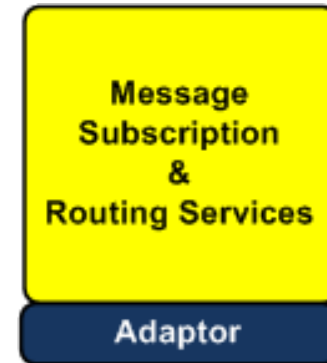


Enterprise Messaging Architecture



Message Subscription & Routing Services

- The “brain” that governs the flow of messages
- Defines who is authoritative source for certain information
- Subscription Database
 - Allows multiple publishers
 - Allows multiple subscribers
 - Publishers do not need to know the subscribers
- Guarantees delivery of messages



Benefits with Modular/Multi-Vendor Solutions

- Allows systems to be plugged in or unplugged without affecting other systems
- Easier and quicker to adopt and take advantage of new solutions
- Allows incremental changes to the enterprise
 - Lower risks than “Big Bang” release
 - Easier to get funding. Big budget may be difficult to come by these days



- Designed for viewing eCTD/NeeS submissions
- Publishing tools neutral
 - View eCTDs/NeeS created by any compliant vendor tools
- (eCTD) Standard-based
 - No proprietary formats or intermediary compilations required
- Much easier to use than an “integrated” or hybrid publishing & viewing tool

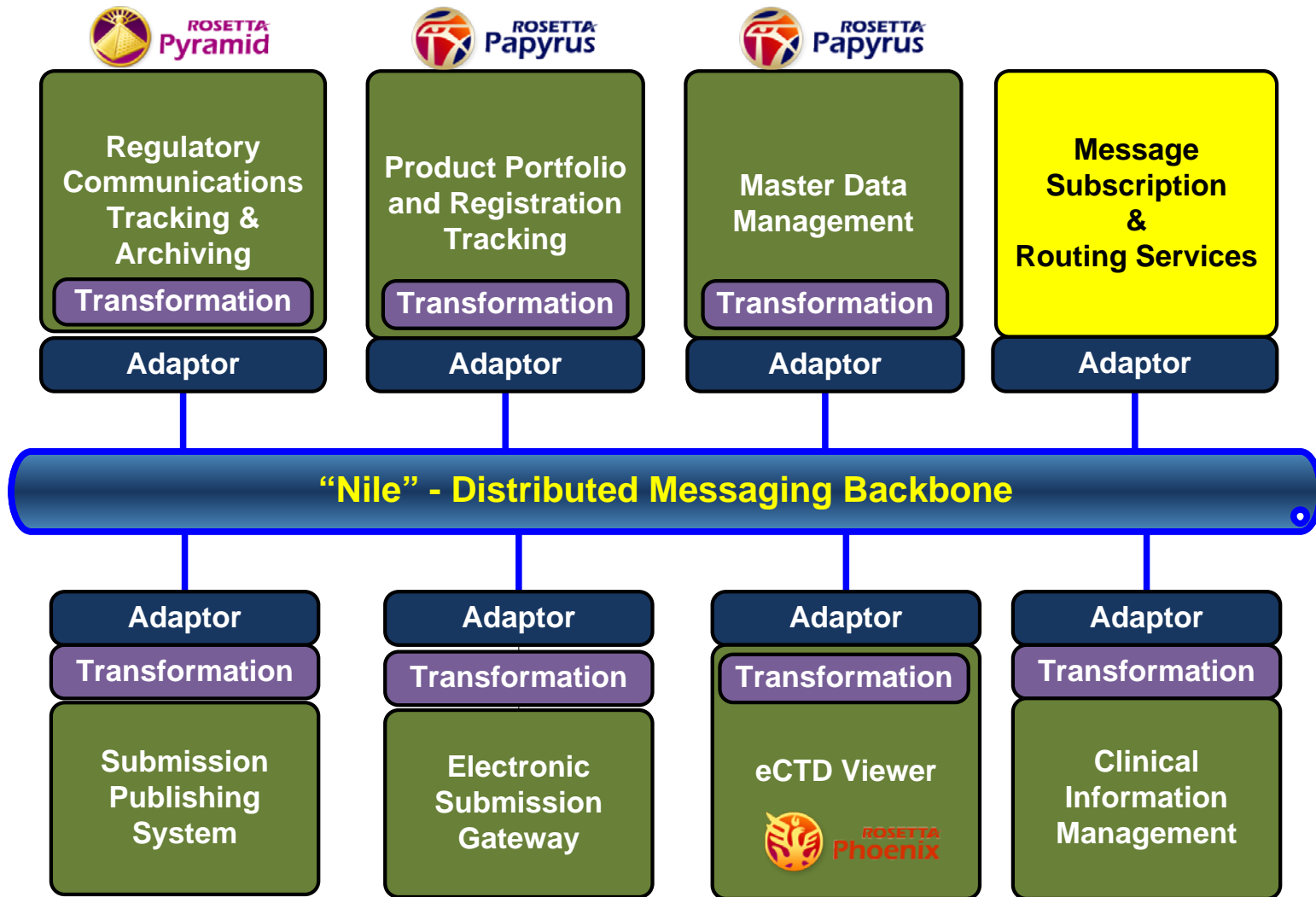


- Records Management System
- Tracks and archives outgoing submissions and incoming correspondence
- Metadata-driven document retrieval
- Auto-index eCTDs from the backbone files
- Built-in eCTD viewer
- Propagates regulatory event messages through ROSETTA *Nile*TM by DoubleBridge Technologies

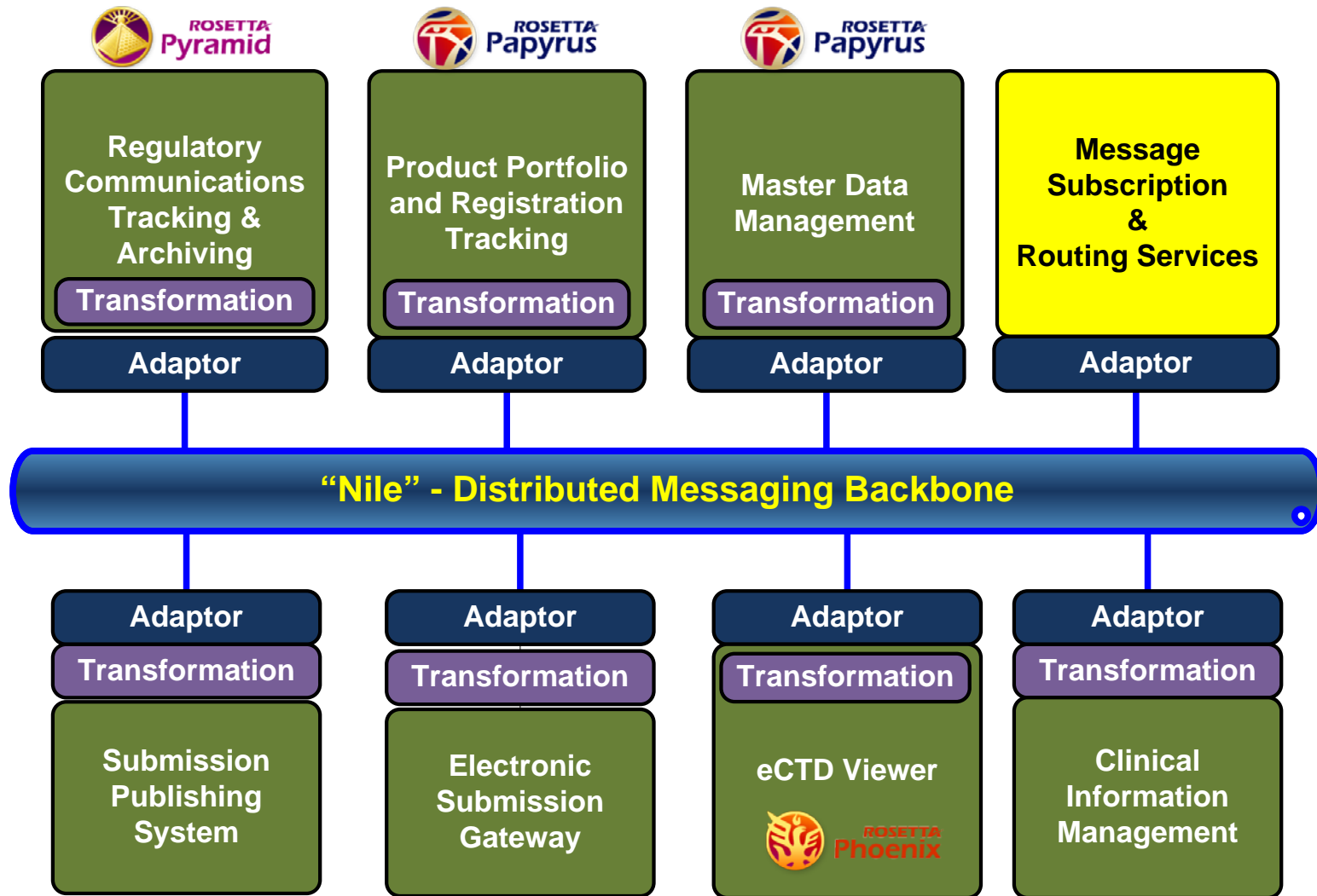


- Master data management
 - Medicinal products
 - Medical devices
- Product life cycle management
- Global registration status tracking
- Supply chain information management
- Propagates product information through ROSETTA *Nile*

Use Case: Market Authorization Approval



Use Case: Litigation/Legal Hold



Conclusions & Recommendations

- Embrace open standards with open arms
- Start to define enterprise messaging standards for internal use
- Consider to build the road (infrastructure) before you get your feet wet on a muddy road (tool)
- Demand your solution vendors to adhere to open and enterprise standards
- Consider and ask vendors the cost of exit before you enter

For more information

Visit www.doublebridge.com/RIM2012
for an updated version of this presentation
with supplemental information

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