

SESSION ID: LS1543CU

CASE STUDY: HOW ZIMMER BIOMET LEVERAGES DIGITAL TRANSFORMATION TO STREAMLINE THE REGULATORY PROCESS

SPEAKER(s):

Linda Heth

Associate Director - IT
Zimmer Biomet

Sajesh Murali

Sr Manager & RIMS Lead
Kalypso

9th of June 2020



Linda Heth

**Associate Director IT,
Zimmer Biomet**

Leading organizational transformation using PLM and integrated systems to advance business collaboration and agility including Value Stream Mapping, Failure Mode and Effects Analysis (FMEA), ISO/TS 16949, ISO 13485 and Quality Management



Sajesh Murali

**Digital Lead,
Kalypso**

Process expert with a strong background in PLM and QMS implementations, including business processes optimization with specialization in requirements, regulatory information management and digital innovation

Zimmer Biomet's Regulatory Information Management (RIMS) journey

RIMS and its impact on global product distribution

Digital enablement at Zimmer Biomet: Kalypso's delivery of IOT and the connected enterprise

Lessons Learned

AGENDA



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ZIMMER BIOMET IN BRIEF

MISSION AND GUIDING PRINCIPLES

Zimmer Biomet's mission is to alleviate pain and improve the quality of life for people around the world. Our commitment to patients shapes all day-to-day decisions at Zimmer Biomet. Relentless customer focus, innovative solutions, disciplined execution and our dedicated people enable us to deliver products and procedures to treat a broad range of musculoskeletal health conditions.*

“Commit to the highest standards of patient safety, quality and integrity.”

*zimmerbiomet.com

ZIMMER BIOMET OVERVIEW



1927

Mr. Zimmer, with fellow salesman J.J. Ettinger, decide to quit their jobs and form the Zimmer Manufacturing Company. They rent a building in Warsaw, Indiana.

1929

Zimmer enters the international market when a Scottish surgeon orders \$1,200 worth of splints.

1942

Zimmer annual sales top \$1 million

1969

Zimmer acquires Little Manufacturing Company, a soft goods vendor in North Carolina. This acquisition led the way for expansion of the Patient Care Division of soft goods production.

1972

Zimmer becomes a subsidiary of New York-based Bristol-Myers.

2015

Zimmer completed its **acquisition of Biomet** forming Zimmer Biomet Holdings

1926

Stainless steel, developed 14 years earlier, is introduced as a corrosion-resistant material for **orthopedic implant devices**.

1927

The Zimmer line of 50 aluminum splints debuts at the American Medical Association meeting in Washington, D.C. The Zimmer splint becomes an immediate leader in its field.

1939-45

World War II spurs development of many new materials and surgical techniques later incorporated into orthopedic use.

1950

Zimmer markets its **first hip prosthesis**, developed in association with Dr. Palmer Eicher.

1971

Zimmer markets its first metal-plastic combination Charnley-type total hip prosthesis.

2001

Zimmer is spun off from **Bristol-Myers Squibb** and begins trading on the New York Stock Exchange

2003-Present

Merger & acquisitions

Source: <http://www.zimmer.co.uk/corporate/about-zimmer/our-history.html>

MULTI-YEAR STRATEGIC PLAN

“We are entering 2020 with a global challenge posed by COVID-19, but also with increased confidence in our team, our core business and our long-term strategic plan to drive sustainable growth and shareholder value.”



**Best and
preferred
place to work**



**Trusted
partner**



**Top
quartile
performer**

Zimmer Biomet and Apple, Inc. have teamed up to set a new standard in digital health by creating mymobility, a digital platform using iPhone and Apple Watch to inform care decisions and create a new level of connection between patients and their surgeons.



Self-directed in-app video exercises allow reduced supervised physical therapy to qualified* patients.



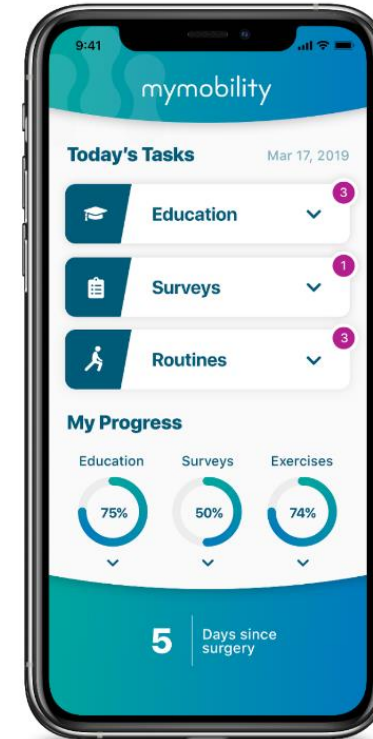
Messaging by text, video or picture is intended to support the patient experience and reduce costs of potential unnecessary visits.



Supports PROMs required quality metric tracking.



Physiologic tracking provides the clinician with insights into their patients' recovery.



AppleWatch is a trade mark of Apple, Inc.

<https://www.zimmerbiomet.com/medical-professionals/zb-connect/mymobility.html>

ZB REGULATORY PAIN POINT THEMES



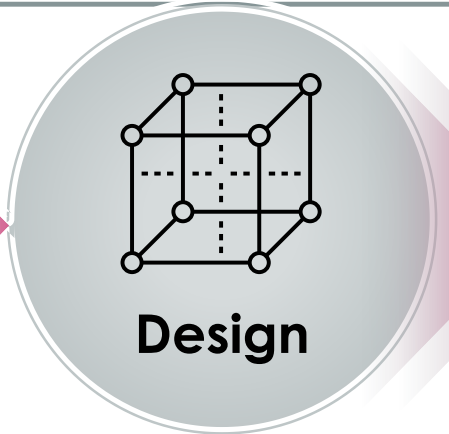
REGULATORY THREAD IN NPI/NPD PROCESS



Planning

Populate Content as design progresses

Collaboration on country-specific design requirements



Design

Regulatory Strategy and Plan

Plan Registrations for Target Markets

Identify/Refine Country Specific Requirements



V&V

Begin submissions and agency correspondence

Set registrations to "Active" status once submissions are approved

Products set to "Released"



Post-Launch

Monitor registrations for expiration

Regulatory Impact Assessment for changes

Ongoing registrations in secondary markets

Kalypso is a professional services firm.

We help our clients discover, create, make and sell better products with digital.

INDUSTRY FOCUS



Consumer



Industrial High Tech



Life Sciences

COMPREHENSIVE CAPABILITIES

Consulting

Digital

Enterprise Technology

Business Process Management & Managed Services

Established in **2004**

260+ Professionals

2020 Acquired by Rockwell Automation

400+ Clients Served

ZIMMER BIOMET & KALYPSO ENGAGEMENT MODEL



Leveraged **pre-configured "Accel" solutions** based on deep industry experience to accelerate delivery



Strategic alignment on broader digital product lifecycle goals



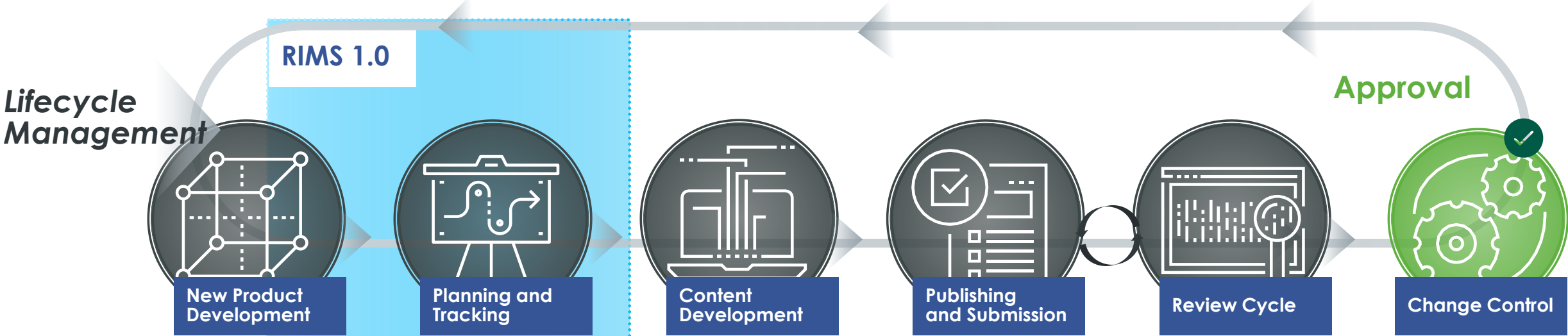
Focused start with regulatory process redesign for targeted groups

*Implementation mantra:
PLM at the heart and RIMs at Start



RIMS AND CONNECTED ENTERPRISE OVERVIEW

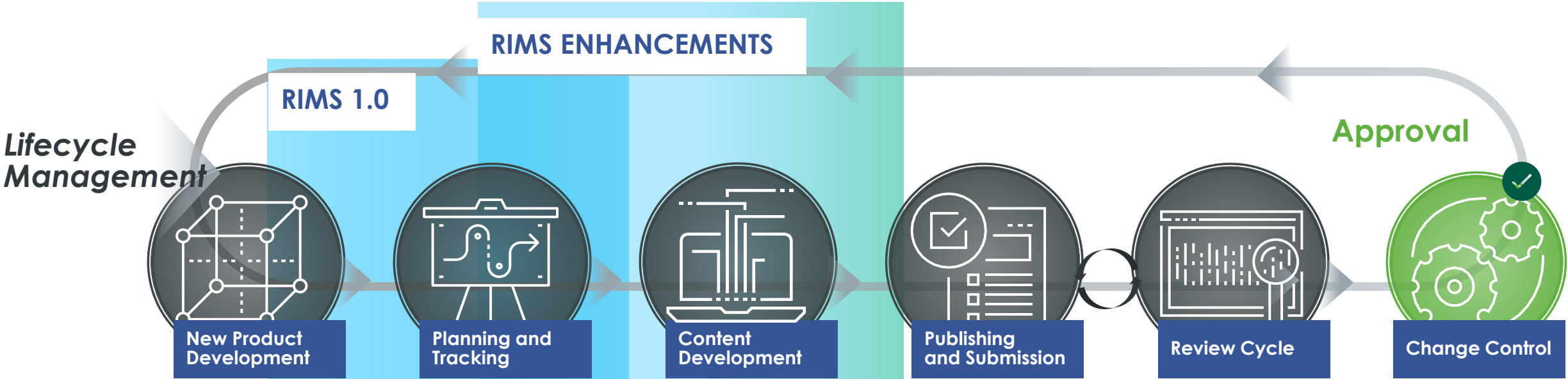
REGULATORY INFORMATION MANAGEMENT (RIM) JOURNEY AT ZIMMER BIOMET



Track Registrations by Product

Identify Expiration Dates

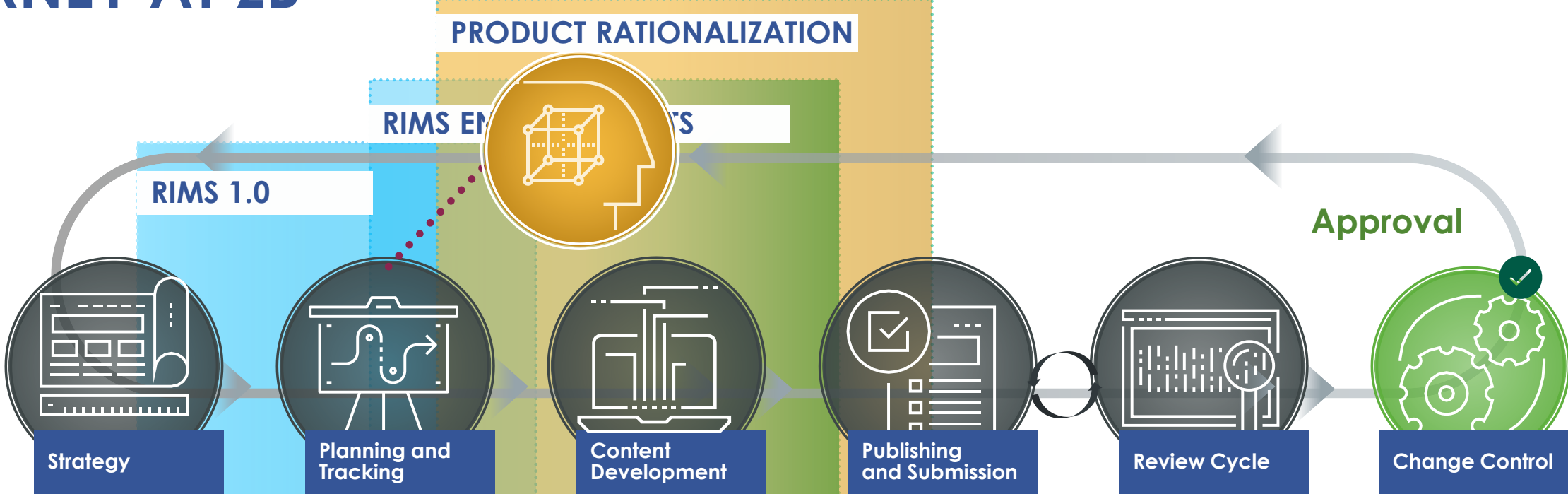
REGULATORY INFORMATION MANAGEMENT (RIM) JOURNEY AT ZIMMER BIOMET



Regulatory reporting requirements

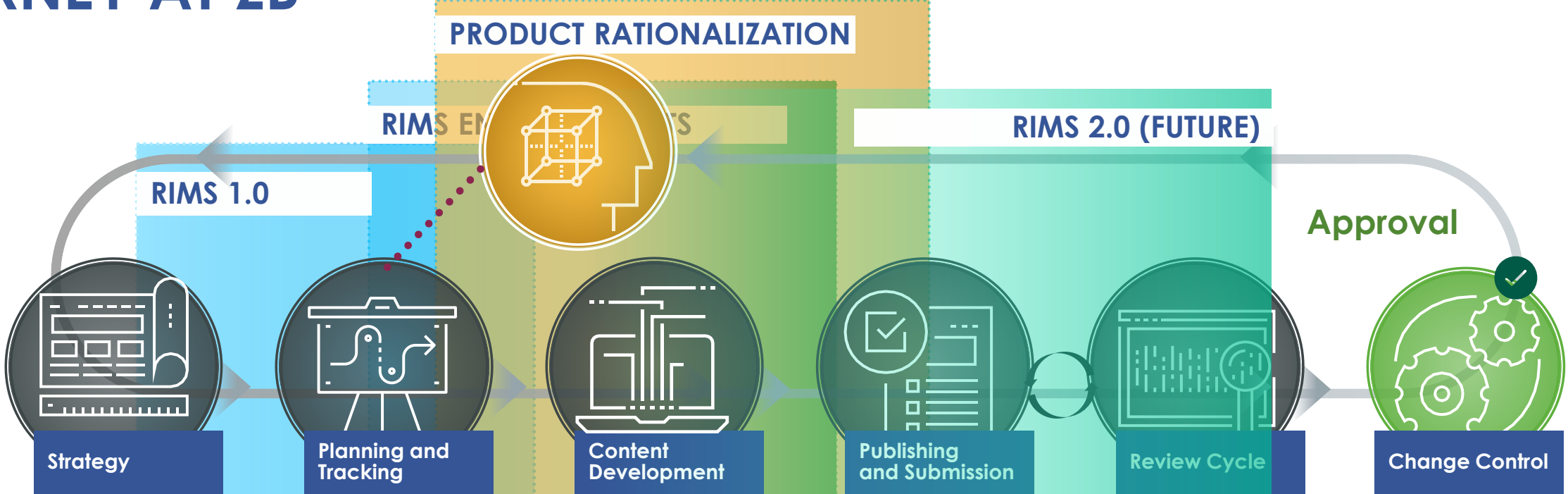


REGULATORY INFORMATION MANAGEMENT (RIM) JOURNEY AT ZB



- 1. Global Product Search
- 2. Discontinuation
- 3. Re-Certification
- 4. Role-based View

REGULATORY INFORMATION MANAGEMENT (RIM) JOURNEY AT ZB



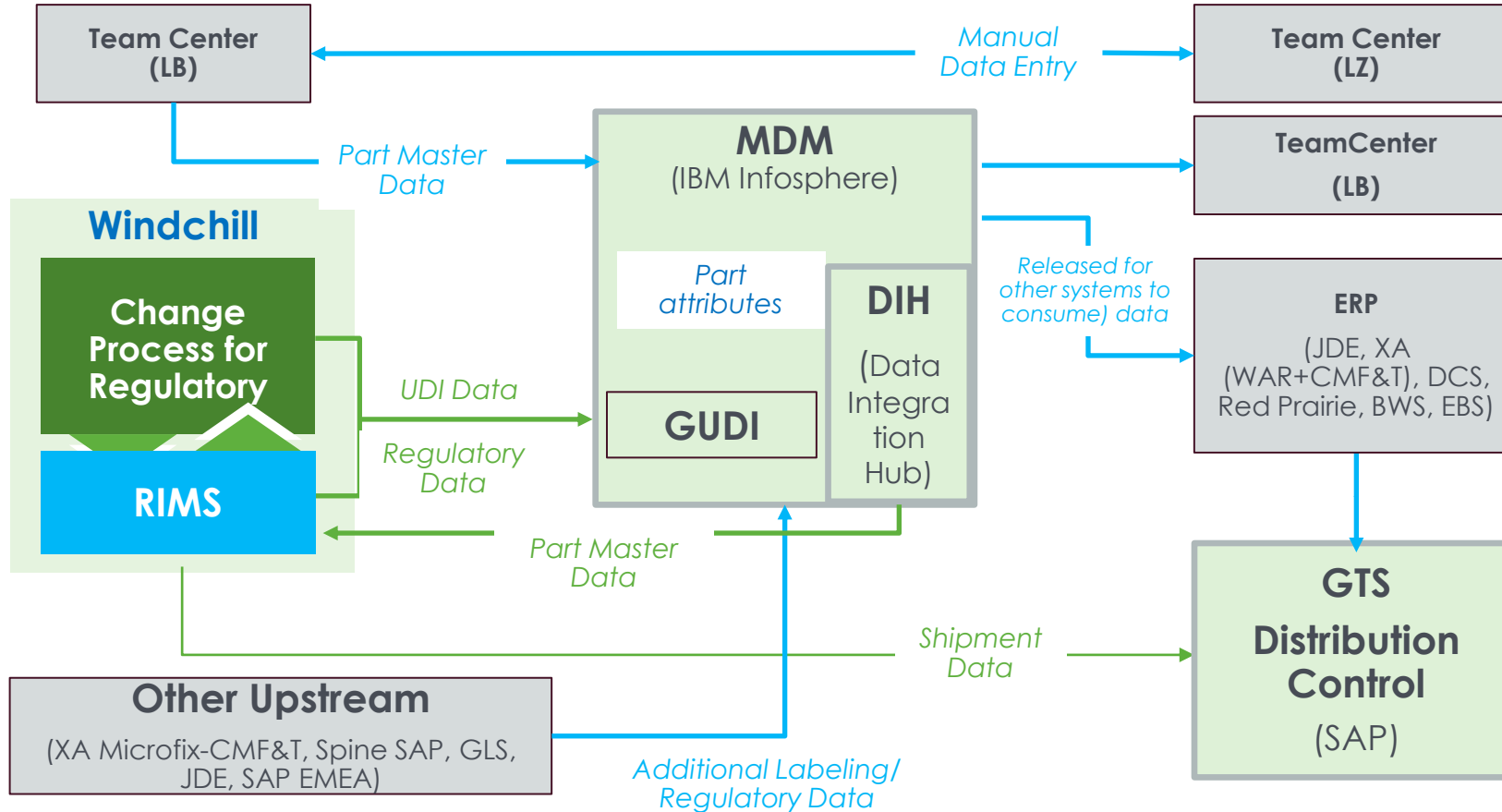
- 1. Submission packaging with Global TOC
- 2. Country specific TOC



SOLUTION OVERVIEW: ZB RIMS PROCESS

Real time process monitoring to power Continuous Improvement

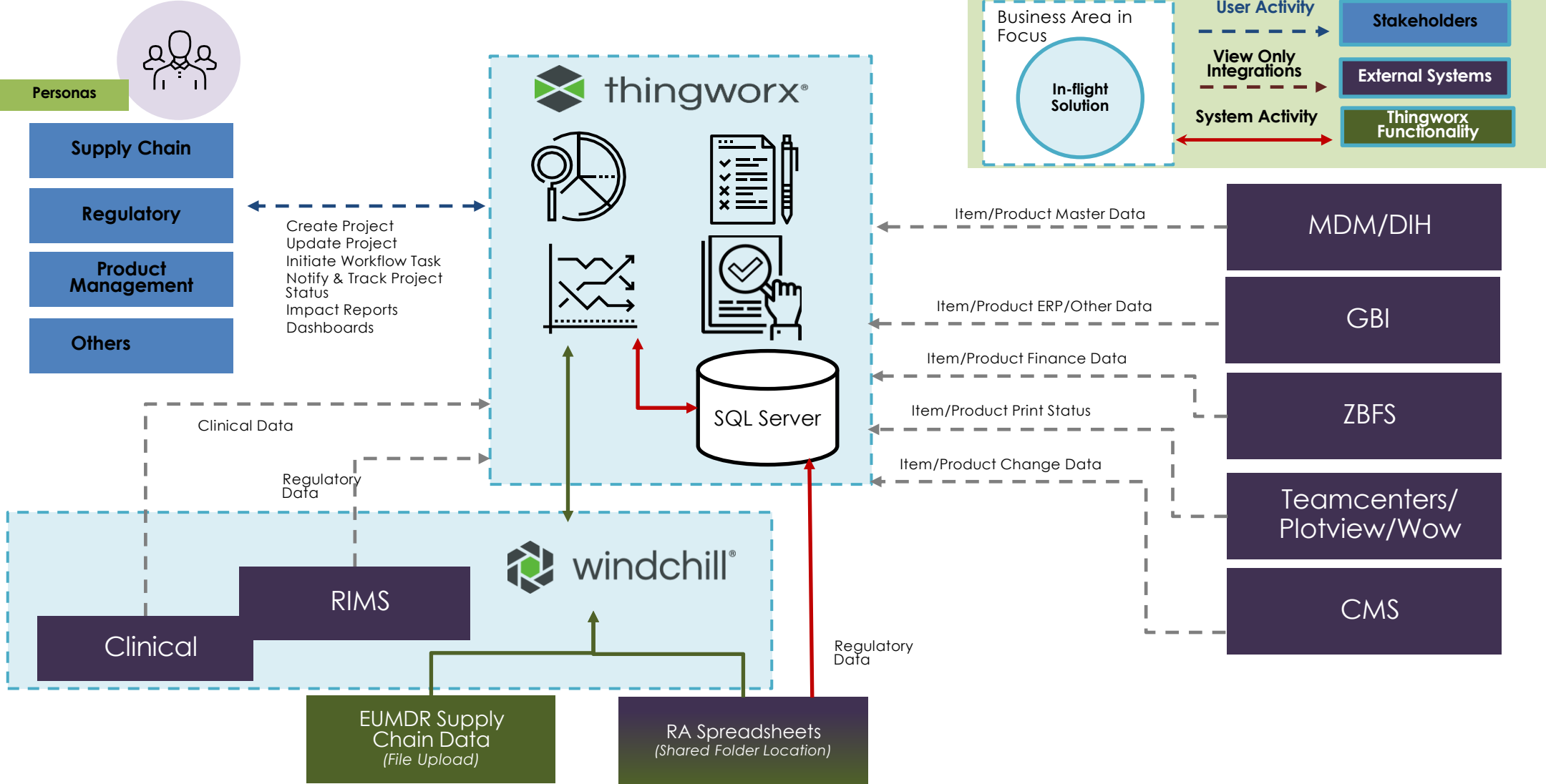
→ RIMS Data → Other Data



Solution benefits

- ◆ Decisions based on data – not intuition
- ◆ Change Controlled Release of Regulatory information to UDI and Distribution control
- ◆ Dependency of regulatory submissions for US (UDI is required before the integration to Distribution is triggered)
- ◆ End to End Product registration tracking and planning

SOLUTION OVERVIEW: THINGWORX AS THE DATA ORCHESTRATION LAYER





LESSONS LEARNED

LESSONS LEARNED – GOVERNANCE



Defined strategy for legacy system disposition and end user adoption



Cross-functional team, with clear responsibilities and strong support from **Leadership** to drive adoption



Delivery following **Agile Methodology** promoting team interactions and close collaboration

LESSONS LEARNED – DELIVERY



Never underestimate Data– align on terminology, data sources and document data mapping



Prototype, iterate and **seek constant user feedback** to achieve optimal UI/UX design and usability



Co-ordinate with multiple teams to ensure proper scope management including integration, data and solution

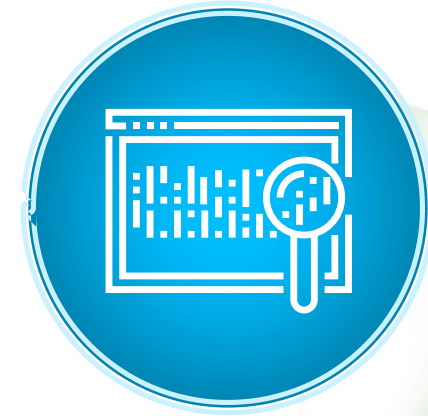
LESSONS LEARNED – THINGWORX



ThingWorx is a **great data orchestration** layer and not so much as a simple reporting layer



Accept **iterative nature** of the the ThingWorx projects and prepare to **revisit hypothesis** and adapt feature set



Anticipate **data quality issues** – availability, reliability and accessibility. Expect some business rules not to be codified

KEY TAKEAWAYS

We looked at how RIMS **facilitates** data management and distribution control by enabling closed loop **change** management.



We leveraged ThingWorx as a data **orchestration platform** that brings data from multiple sources to enable decisions to be **data driven** than intuition-based



We shared **lessons learned** and advice applicable for any organization embarking on the digital journey.



WANT TO LEARN MORE?

VISIT

WWW.KALYPSO.COM/
LIVWORX2020

#LIVWORX

Thank you!

Linda Heth



linda.heth@zimmerbiomet.com



[linkedin.com/in/lindaheth](https://www.linkedin.com/in/lindaheth)

Sajesh Murali



sajesh.murali@kalypso.com



[linkedin.com/in/sajesh-murali-2656b53](https://www.linkedin.com/in/sajesh-murali-2656b53)



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