

The Digital Transformation of the Medical Industry: Roadmap to adopt a Model-centric approach

Cristina Martínez
Edwards Lifesciences
Advanced Technology/ CAD Engineering Services



Presenters Bio

Global Product Data Interoperability Summit | 2022



[Cristina Martinez | LinkedIn](#)

Cristina_Martinezvillalba@edwards.com

Education

Universidad Autónoma de Baja California, MX

- BS, Mechanical Engineering, Thermal & Fluids
- MBA, Human Resources & Finance
- PhD, Engineering Management (candidate)

Industry

Medical, Aerospace and Automotive

- Mechanical Design Engineer
- Data Exchange Engineer
- MBE Tools & Process Development Lead
- Geometry Validation Lead
- Sr Manager, Business Solutions

Agenda

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1 – Edwards
Lifesciences
Overview

2 – Current
State

3 – The
Journey

4 – Our
Approach

5 –
Recommen
dations

6 – Lessons
Learned

Edwards Lifesciences

- The global leader of patient-focused medical innovations for structural heart disease and critical care monitoring.



Edwards

Edwards Lifesciences at a Glance



600K⁺
Patients Treated With
Transcatheter Therapies



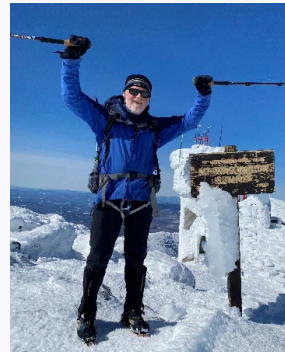
95%⁺

Sales from Products with
#1 Global Market Share

~2,000
Engineers



Investment in R&D
17%
of 2021 sales



16,000⁺
Global Employees



50%⁺
Millennials and Generation Z



7

Manufacturing Locations
Around the World



Resilient Supply
Chain



80%⁺
Charitable employee
engagement



Unleashing our potential ...

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FROM



Siloed processes and heavy manual work (processes from the 90's)



Document-centric makes it difficult to share/connect data



Disconnected product data & systems



Multiple partial "PLM solutions"

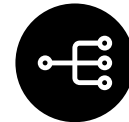


Complex regulatory landscape



Frustrated employees

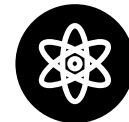
TO



Standard, leading processes integrated across the E2E value stream



Enriched, clean, & connected product data



"Single Source of Truth" for product data



One product innovation platform



Reduced compliance risk



Empowered employees

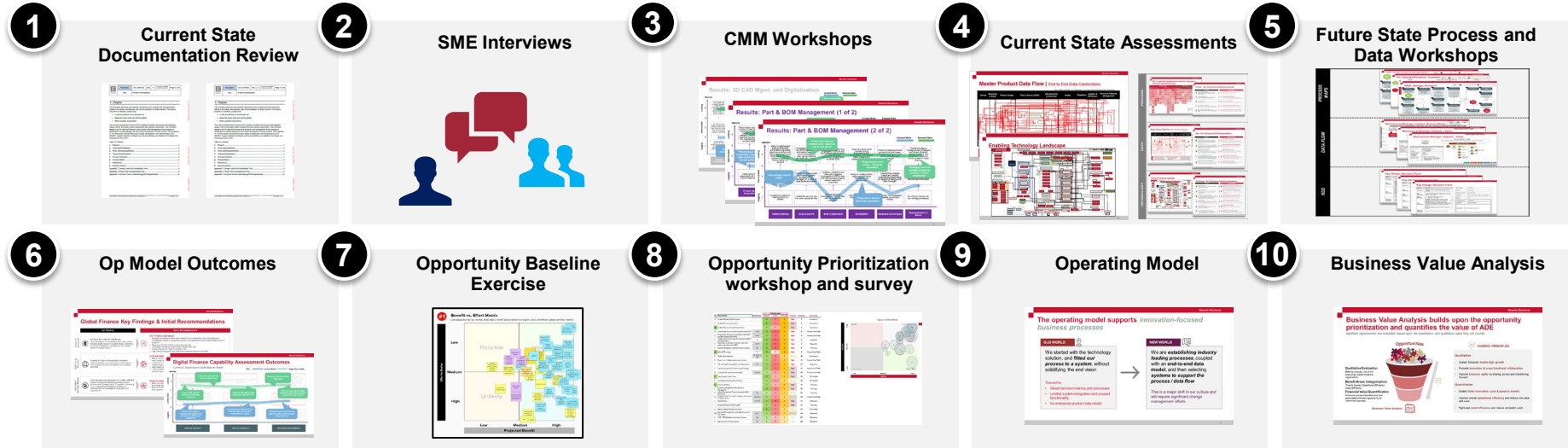
Digital Transformation Roadmap Approach

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Approach

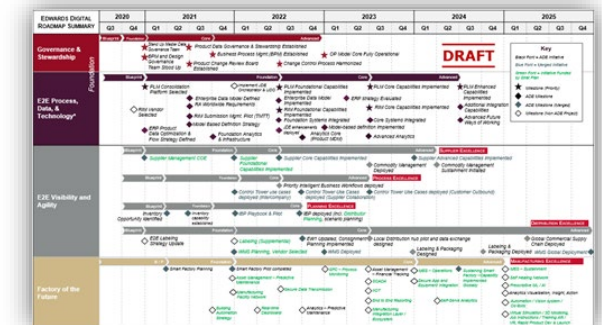
Create a **cohesive plan to close capability gaps** prioritized by impact to the business, rough order magnitude estimate, workplan, and timeline of required activities to implement target architecture, and prioritize and sequence recommendations based on dependencies and value

Inputs



Goal

- Provide an **integrated and coordinated value realization plan** with a customized approach to meet Edwards' objectives and **realize value at scale while minimizing business risk** – Creating meaningful value by transforming patient care



Transformation Strategy

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OUR TRANSFORMATION STRATEGY...

1. **PROCESS-LEADING**
2. **DATA-DRIVEN**
3. **HUMAN-CENTERED DESIGN THINKING**
4. **TECHNOLOGY ENABLED, AGILE DELIVERY**
5. **ONE TEAM, ONE PLAN**

...ENABLES VALUE



Benefits

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Digital Product Development



Launch products faster



Enable product innovation



Deliver unrivaled quality from design to commercialization



Unlock opportunities to transform patient lives

Digital Supply Chain



Paperless & smart manufacturing



Increased operational leverage

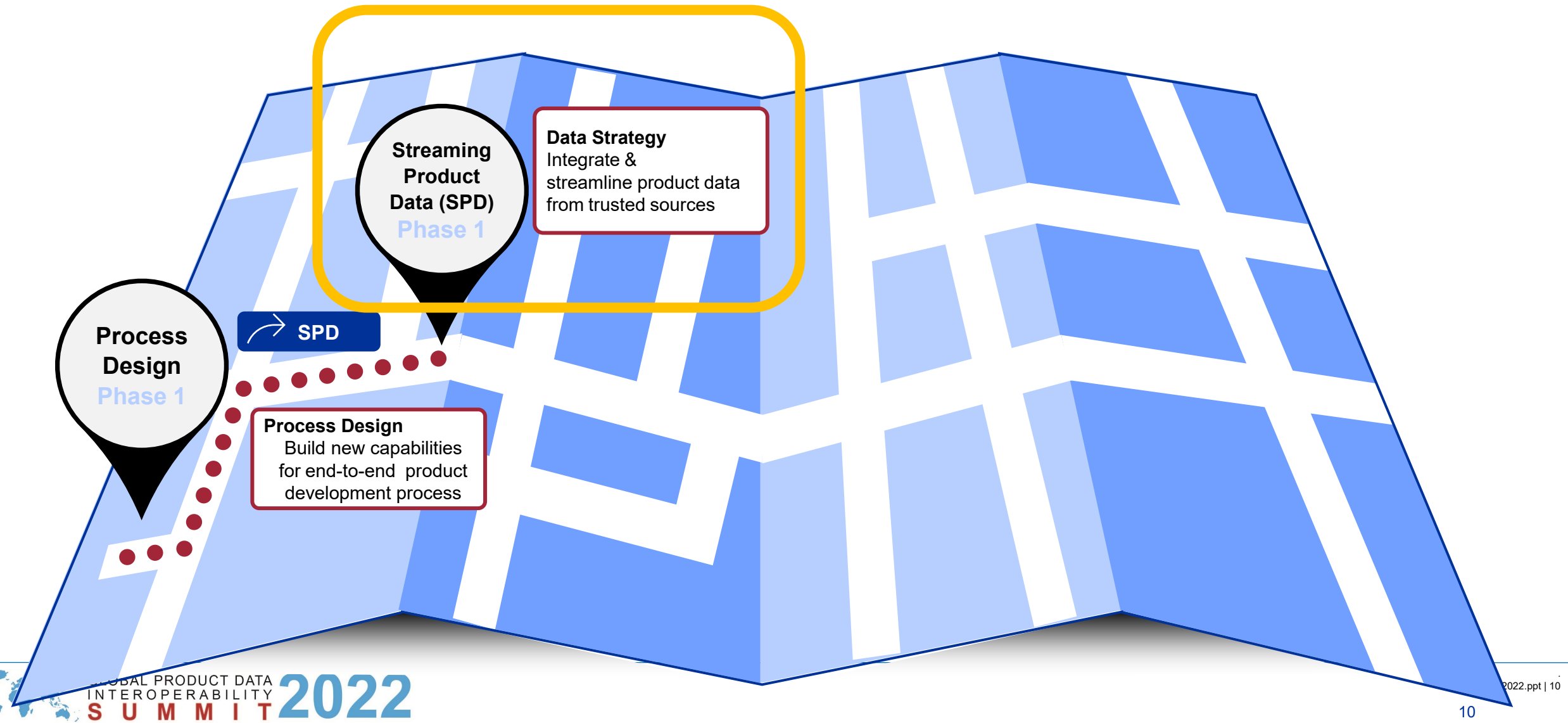


Cross-enterprise and external collaboration

Patient-Focused Culture motivates and guides our global team

Our Journey to Reimagine the Future

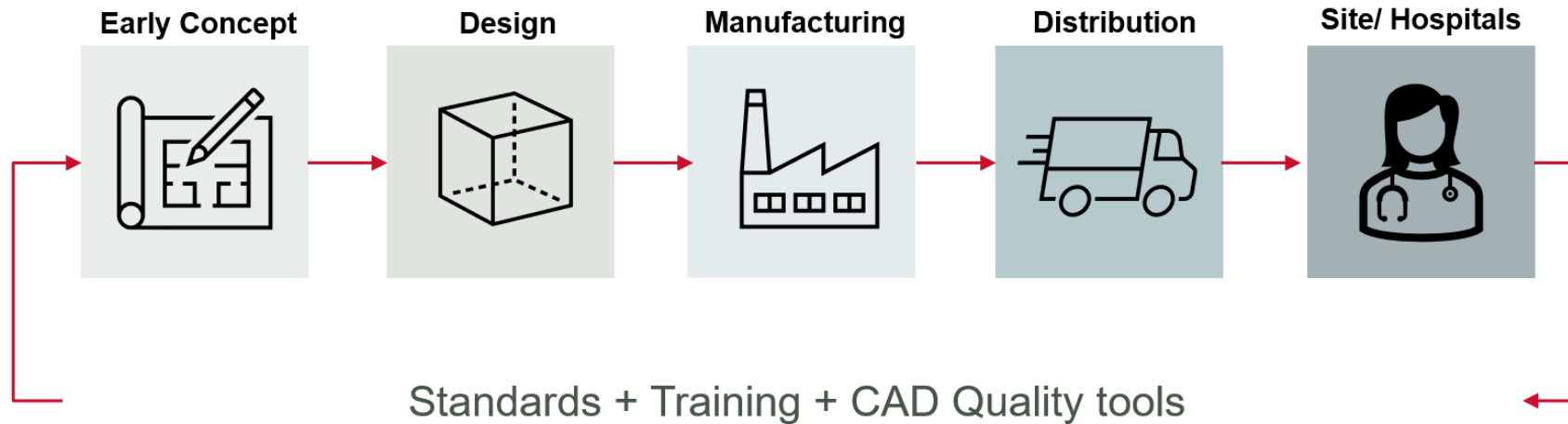
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What is 3D Trusted Data (3DTD)?

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Ensuring CAD data is accurately produced in compliance to Edwards Design Standard, allowing us to serve more patients



Reaching our goals will require incremental steps ...

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Current State

■ **Product Definition**

- Drawing derived from Model but disconnected

■ **EBOM**

- EBOM not linked to the CAD models

■ **Analysis**

- New models created to support analytic Activities

■ **Checking & Model Quality**

- 2D drawing validated
- 3D model not validated



Long Term Goal

■ **Product Definition**

- Model contains complete product definition

■ **EBOM**

- MBOM/other BOM definition is defined using CAD

■ **Analysis**

- Native CAD model is reused as analytic model without model modifications

■ **Checking & Model Quality**

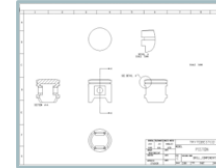
- 3D Product definition validated during model creation. Derivatives validated at creation.

Evolving CAD Data for Digital Transformation

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Drawing Centric Environment

We create 3D Models to produce the 2D Drawing and use those drawing are used to produce our products



Understand current state and gaps

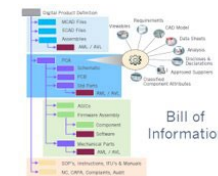
3D Trusted Data (3DTD) Program

- Organizational Change Management
- Multi- CAD Data Integrity
- Standards & Tools
- CAD Training

One Product Innovation Platform

Part Centric Environment

- Enable PLM functionality



Model Based Definition

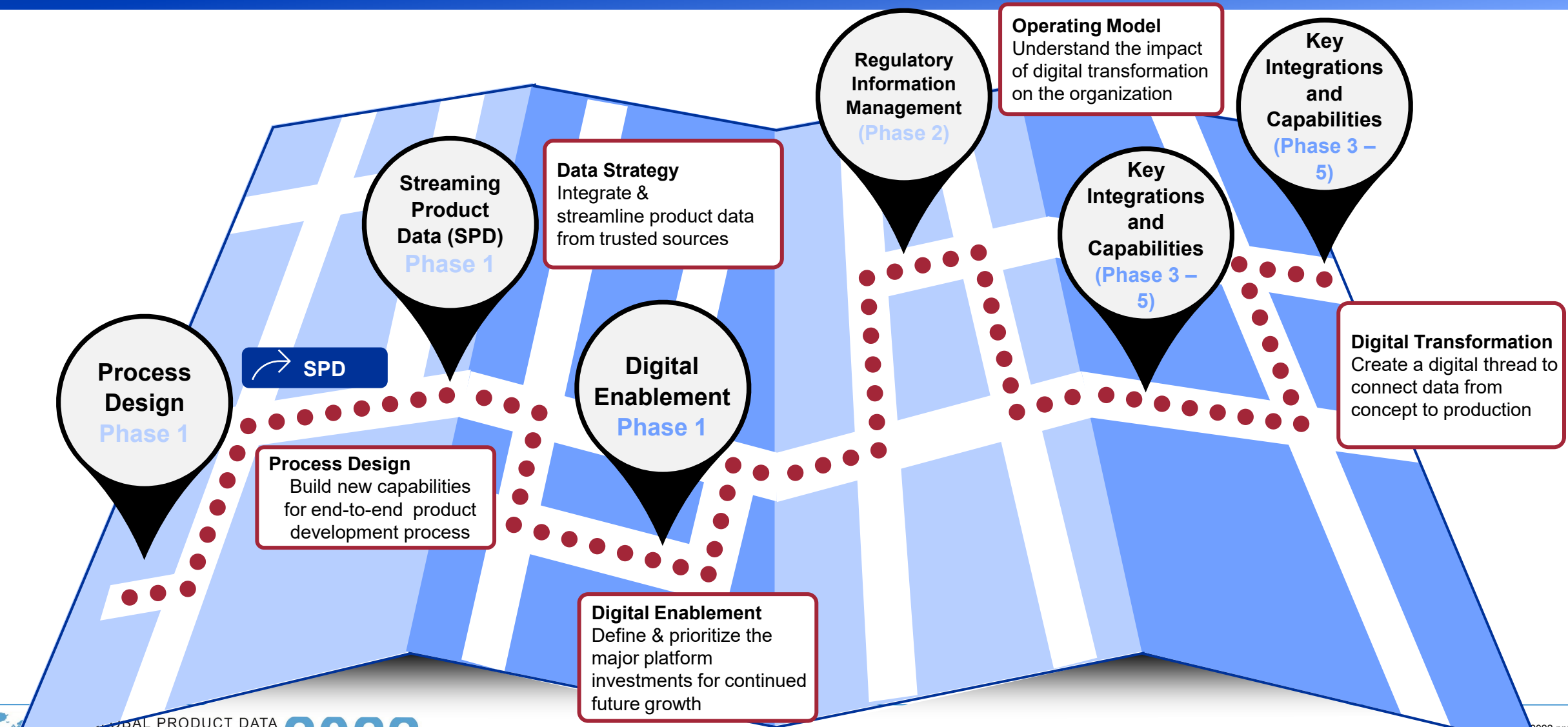
In the Future we will create 3D Models to produce products (not to produce drawing)

Level 6	Model Based Definition - Integrated Manufacturing - Integrated Internal Interchange - Primary Information: Digital Product Definition Package & 3D CAD
Level 5	Model Based Definition - Integrated Manufacturing - Integrated Internal Interchange - Primary Information: Digital Product Definition Package & 3D CAD
Level 4	Model Based Definition - Integrated Manufacturing - Integrated Internal Interchange - Primary Information: Digital Product Definition Package & 3D CAD
Level 3	Model Based Definition - Integrated Manufacturing - Integrated Internal Interchange - Primary Information: Digital Product Definition Package & 3D CAD
Level 2	Model Based Definition - Integrated Manufacturing - Integrated Internal Interchange - Primary Information: Digital Product Definition Package & 3D CAD
Level 1	Model Based Definition - Integrated Manufacturing - Integrated Internal Interchange - Primary Information: Digital Product Definition Package & 3D CAD
Level 0	Model Based Definition - Integrated Manufacturing - Integrated Internal Interchange - Primary Information: Digital Product Definition Package & 3D CAD



Our Journey to Reimagine the Future

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Recommendations

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- **Discover – Anticipate – Partner – Transform**
- **Perform an End-to-End Gap Assessment**
 - Run a Proof of Concept (POC) to identify and tackle main challenges
 - Begin testing design ideas and work through Key Design Decisions
 - Expose users to the new system
 - Identify critical areas of integrations, workflows and customizations
- **Early Gaps & Risks Identified & Mitigation Plans in place. KDDs tied to POC scope dispositioned & ratified.**
- **Identify the Organizational Change Mgt. challenges with the Business Transformation team, targeting areas of focus.**

Lessons Learned ... so far

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- **Know the 'Why'** of the digital transformation and have a **[flexible] plan**
 - Cost considerations
 - Learning from failure
- **Leadership alignment**
 - Who leads the transformation?
 - Ownership versus participation
 - Priorities reflected in action
- **Culture**
 - Start with **leadership**
 - Collaborate on a new culture identity
 - Decide on a mechanism to **drive change**
 - Invest in **change management** and **communication**
- Draft a 'wireframe' **Operating model** and be prepared to change it





Edwards