IHE & SysML/MBSE –
Moving from Doc to Model Centric

considering

Unity Consulting's MBSE 2021.03.25 Webinar Perspectives

IHE TF Development Process – *20+ Years On!*

Consider:

- ✓ IHE's TF Development process is rooted in life 20+ years ago (Document Centric)
- ✓ To support more complex heterogeneous SES MDI environments …
  The IHE processes must align with state-of-the-art
  MedTech product development tools & processes
  supporting the ***Total Product Lifecycle***
- ✓ Recognizing there is a tension between …
  SysML / MBSE (OMG's Systems Modeling Language &
  Model Based System Engineering)
  TDD / ATDD / BDD (Test / Acceptance Test / Behavior Driven
  Development – agile methods)
- ✓ Safety Critical / ***"regulatory submission ready"*** IHE solutions must include MBSE

MBSE @ Unity: *Serendipitously Timely Webinar!*

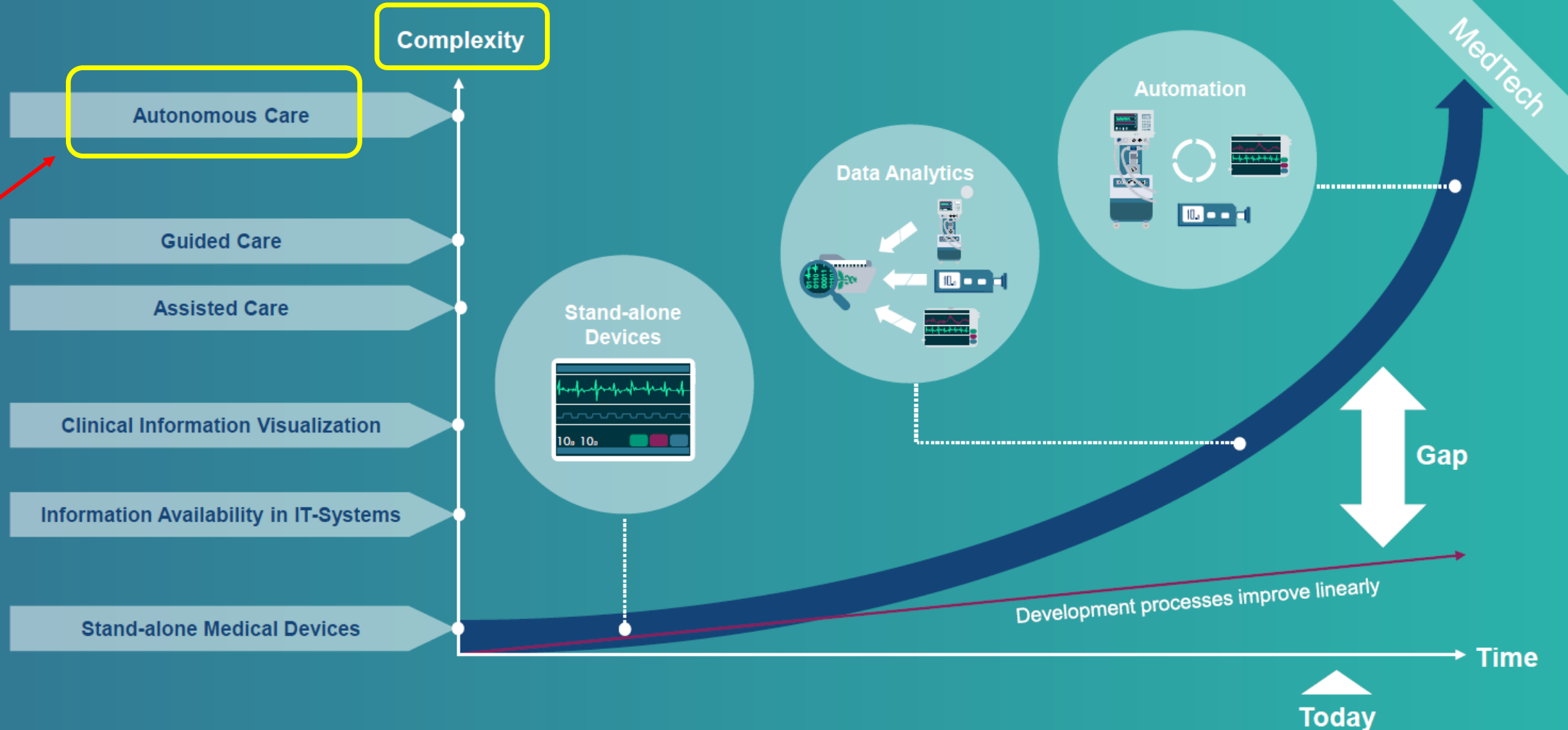# MBSE @ Unity: *Complexity @ Autonomous Systems*

Reality for SDC/SDPi Ecosystems

JHU/APL MDIRA Objective

The Need for Systems Engineering
Complexity of development is increasing exponentially

Complexity

Autonomous Care

Guided Care

Assisted Care

Clinical Information Visualization

Information Availability in IT-Systems

Stand-alone Medical Devices

Stand-alone Devices

Data Analytics

Automation

MedTech

Gap

Development processes improve linearly

Time

Today

UNITY
CONSULTING & INNOVATION

25.03.2021   Webinar MBSE – Master Complex Development More Easily

Confidential   @ UNITY   8

MBSE @ Unity: *Address TPL $$$*

To help MedTech developers adopt / implement / support IHE-based technologies ...
TPL development costs must be directly impacted

Defined Costs vs. Incurring Costs during the Life Cycle

UNITY CONSULTING & INNOVATION

| Concept | Development | Production | Utilization / Support | Retirement |

Defined costs

70%

85%

95%

100%

Cost for deficiencies removal

Factor 500...1000

Factor 20...100

Lifecycle costs over time

Factor 3...6

Incurring costs

8% 15% 20% 50% 100%

The 1st phase is of utmost importance!
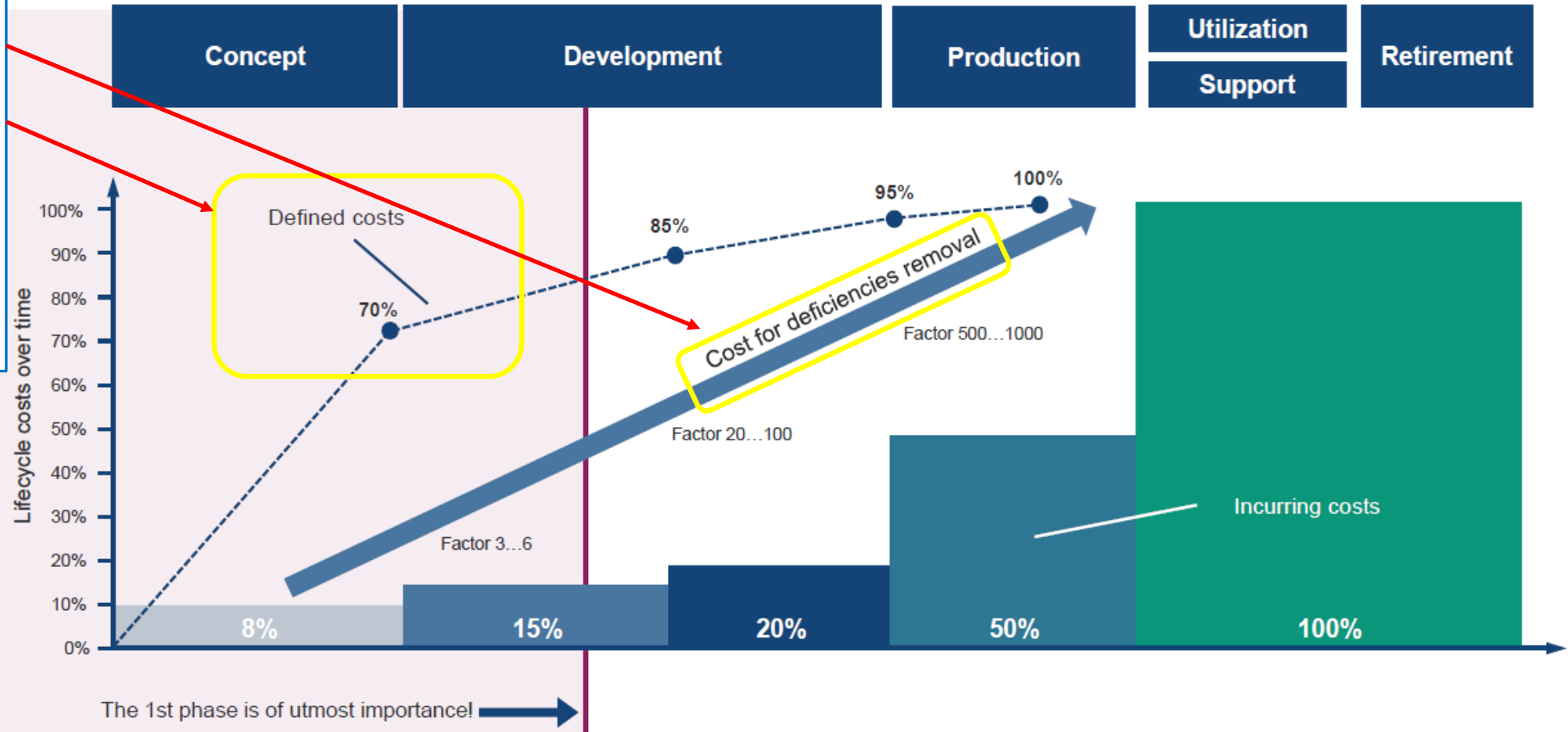
MBSE @ Unity: *From Doc to Model-Based SE*

Document-based vs. Model-based approach

UNITY CONSULTING & INNOVATION

IHE 20+ Year History …

IHE Model-based Source of Truth!
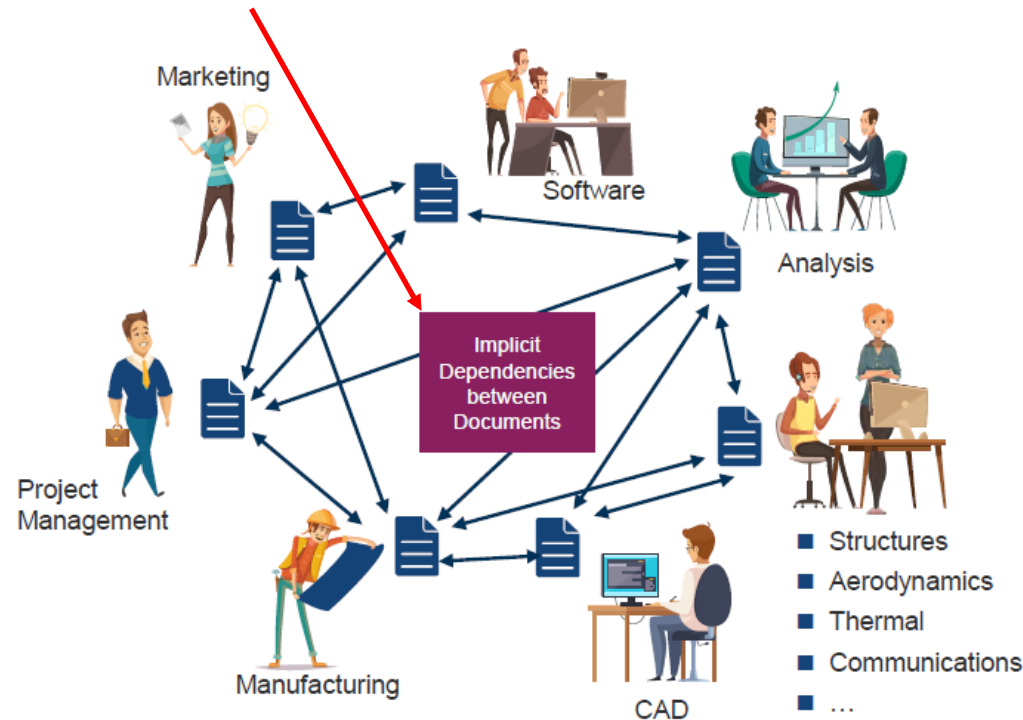
Traditional systems engineering

Model-based systems engineering

Madni et.al. 2019

MBSE @ Unity: *SysML/MBSE ... starting @ RI Today*

MBSE supports RFLP approach
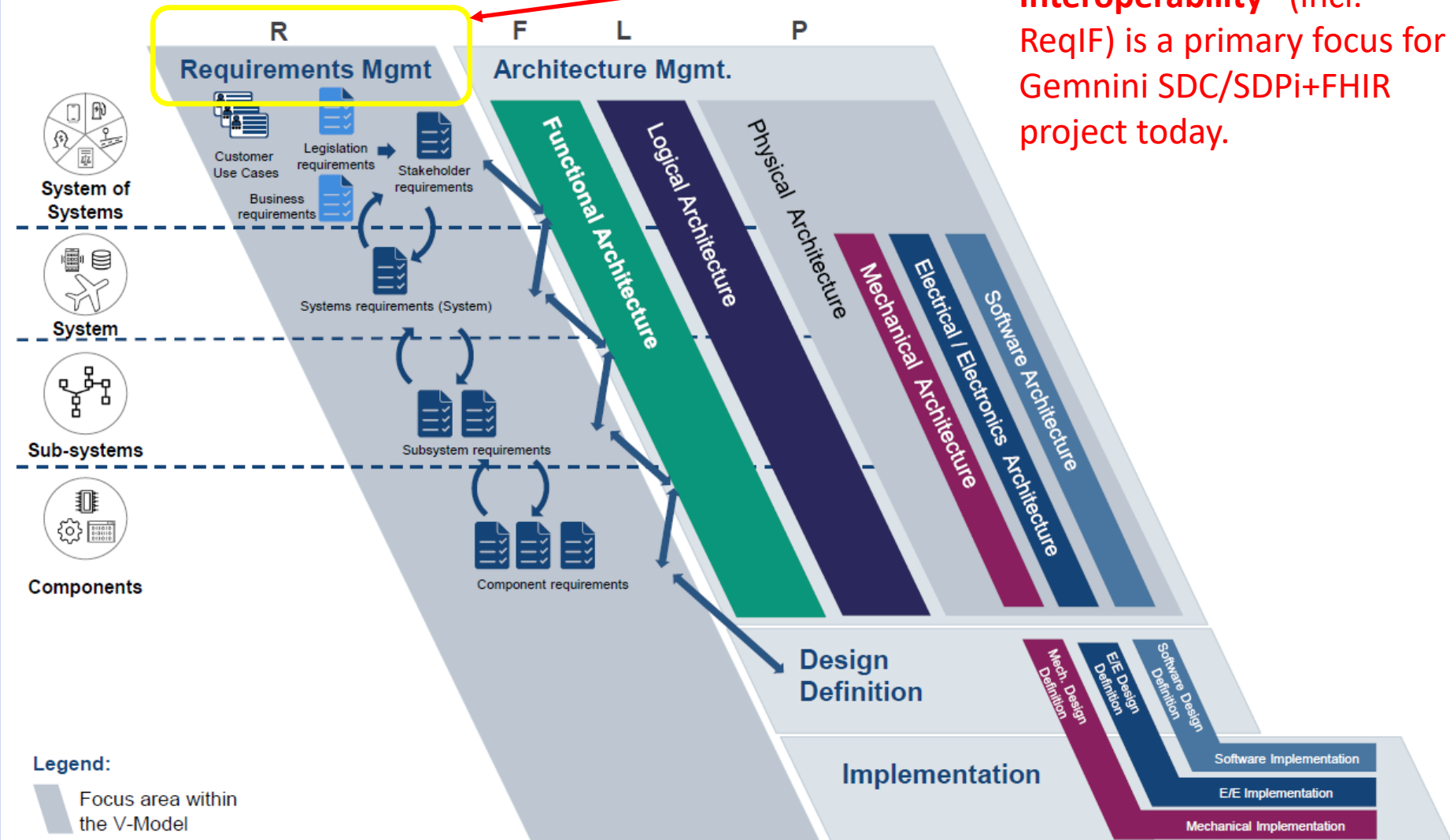
"**Requirements Interoperability**" (incl. ReqIF) is a primary focus for Gemnini SDC/SDPi+FHIR project today.

IHE TF Development Process – *20+ Years On!*

Conclusions:

- ✓ MBSE / SysML hits at the core value propositions for the **IHE MedTech community**
- ✓ "Interoperable" MBSE / SysML is a "futures" proposition … but we can start today
- ✓ ***Requirements Interoperability*** is a "safe" next step
- ✓ "Model Repositories" as IHE TF Artifacts represent a "single COMPUTABLE source of truth"
- ✓ MBSE can lower the cost-barrier-of-entry for the adoption / implementation of IHE-based solutions … starting with the development costs at the earliest stages of design
- ✓ Unity: "The main function of SE is to facilitate communication!"

IHE TF Solutions are 100% about … COMMUNICATION!

Challenge:

- ➢ MedTech Developers cannot / will not do the heavy lifting – research! – to get critical mass on Interoperable MBSE / SysML artifacts … ***Catalytic project support necessary!***