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The Agile Transition of Roche Diabetes Care

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The Agile Transition

Agile Transition of Roche Diabetes Care
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Agile Transition of Roche Diabetes Care
Agenda

- Overview
- **Why** change
- **What** was the cause
- **How** we are transitioning
- **Where** we are in our transition
- Wrap up

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Agile Transition of Roche Diabetes Care

Overview

Due to the high levels volatility in our environment, Roche Diabetes Care is taking the initiative to move from a traditional development model to Agile

While the initial focus is on R&D, changes are happening across the organization with many areas outside of R&D looking for ways to participate in agility

Focus on

- Factors driving change
- Our path towards agility
- Challenges and successes

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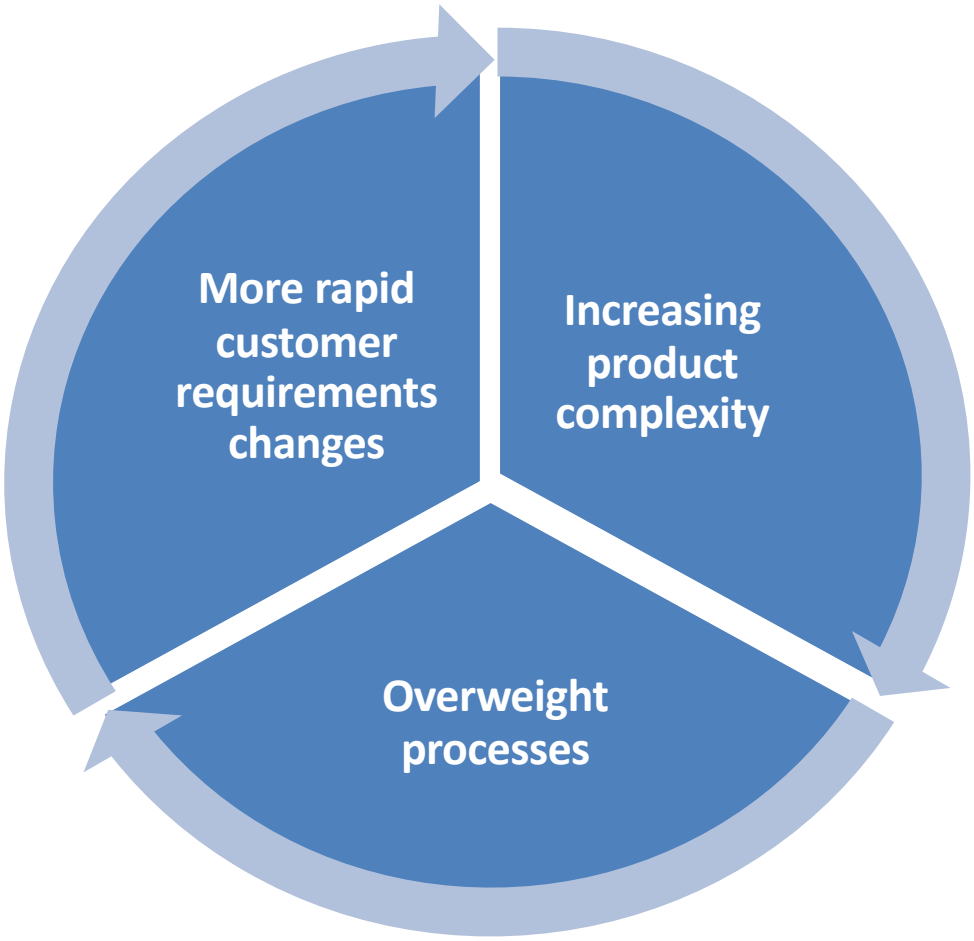
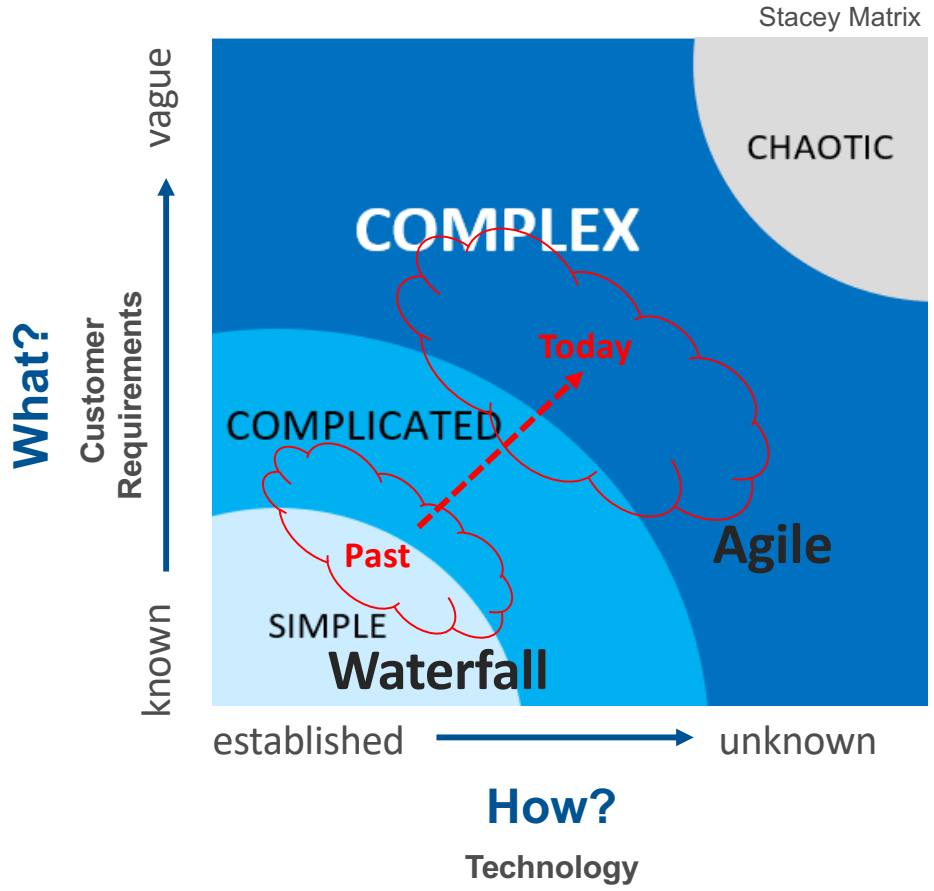
Why Agile Transition of Roche Diabetes Care?

Our world is getting more and more complex



Speed of changes and complexity increase, unscheduled changes become more prevalent, companies slow to react

Why Agile Transition of Roche Diabetes Care? *Our world is getting more and more complex*



Why Agile Transition of Roche Diabetes Care?

Waterfall or Agile? - It depends…

Scope Uncertainty & Effort Uncertainty

Predictive

Waterfall

- ☺ Emphasizes efficiency (minimum cost, duration)
- ☺ Performs well when work is well understood
- ☹ Performs poorly when uncertainty is high

Adaptive

Agile

- ☺ Emphasizes adaptability to rapid change
- ☺ Enables detailed short-term planning
- ☺ Evolves longer-term spec's, plans over time
- ☹ Overhead of enabling change is costly for predictable work

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Historical Evolution of Agile

Manu-facturing

1900's

Lean Manufacturing

1950's – 1970's

Lean Product Development

1990's

Agile Codified

Early 2000's

2010's - present

Changes to Manufacturing

Changes to Product Development

Changes to Organization

Digitalization …

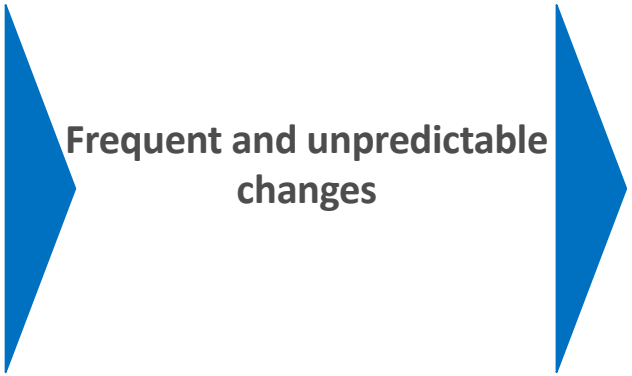
…is changing our World

Customer needs

Technologies

Competition

Business models



V **volatility**

U **uncertainty**

C **complexity**

A **ambiguity**

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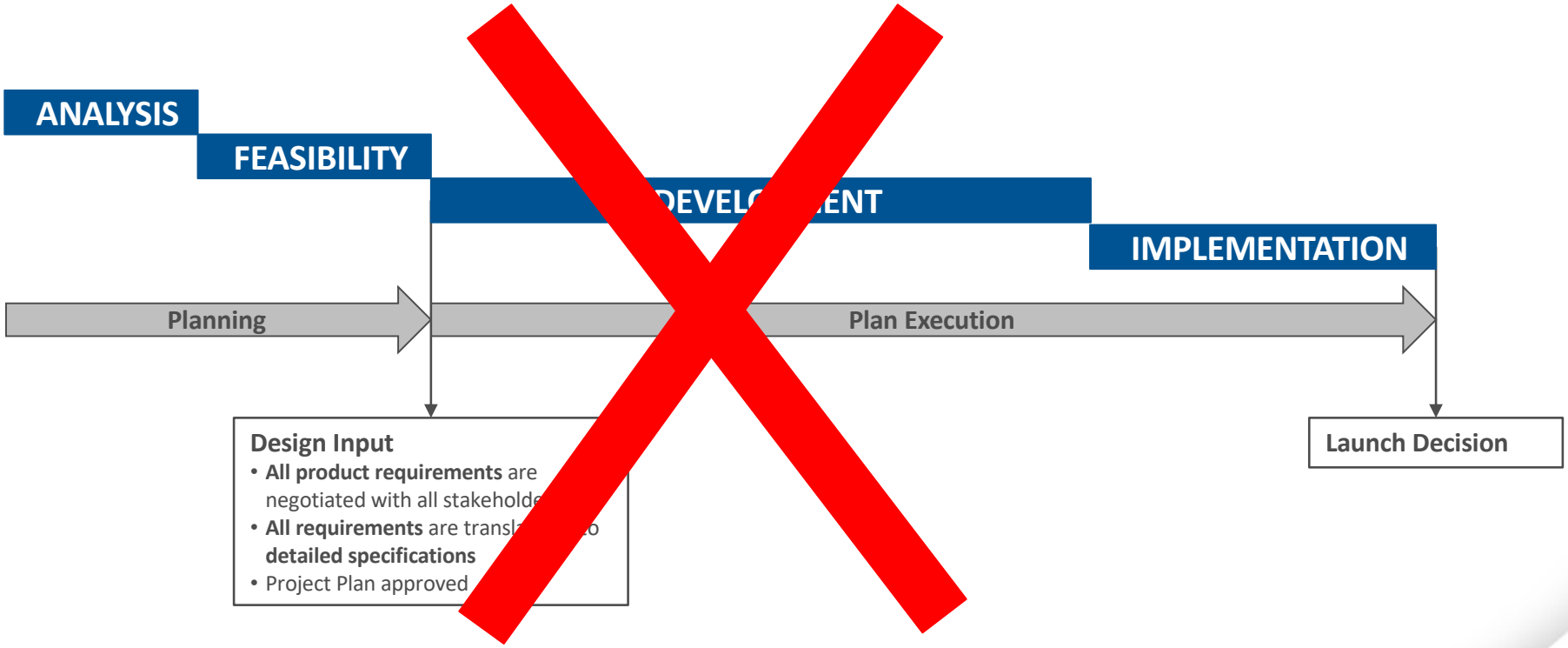
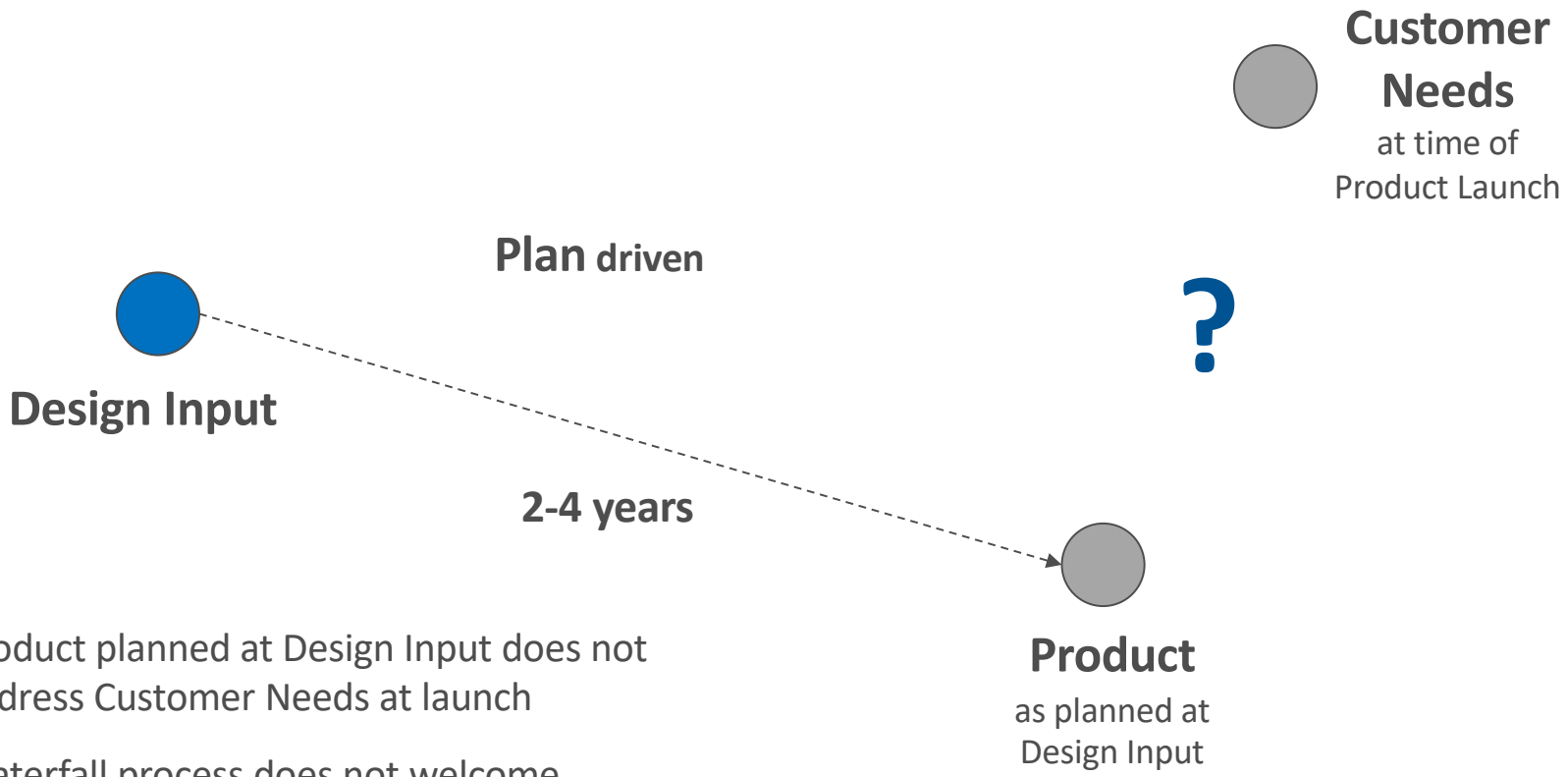
…but what does VUCA mean for Development?

The traditional Waterfall Development Process



…but what does VUCA mean for Development?

The linear Waterfall Process does not work



- Product planned at Design Input does not address Customer Needs at launch
- Waterfall process does not welcome change

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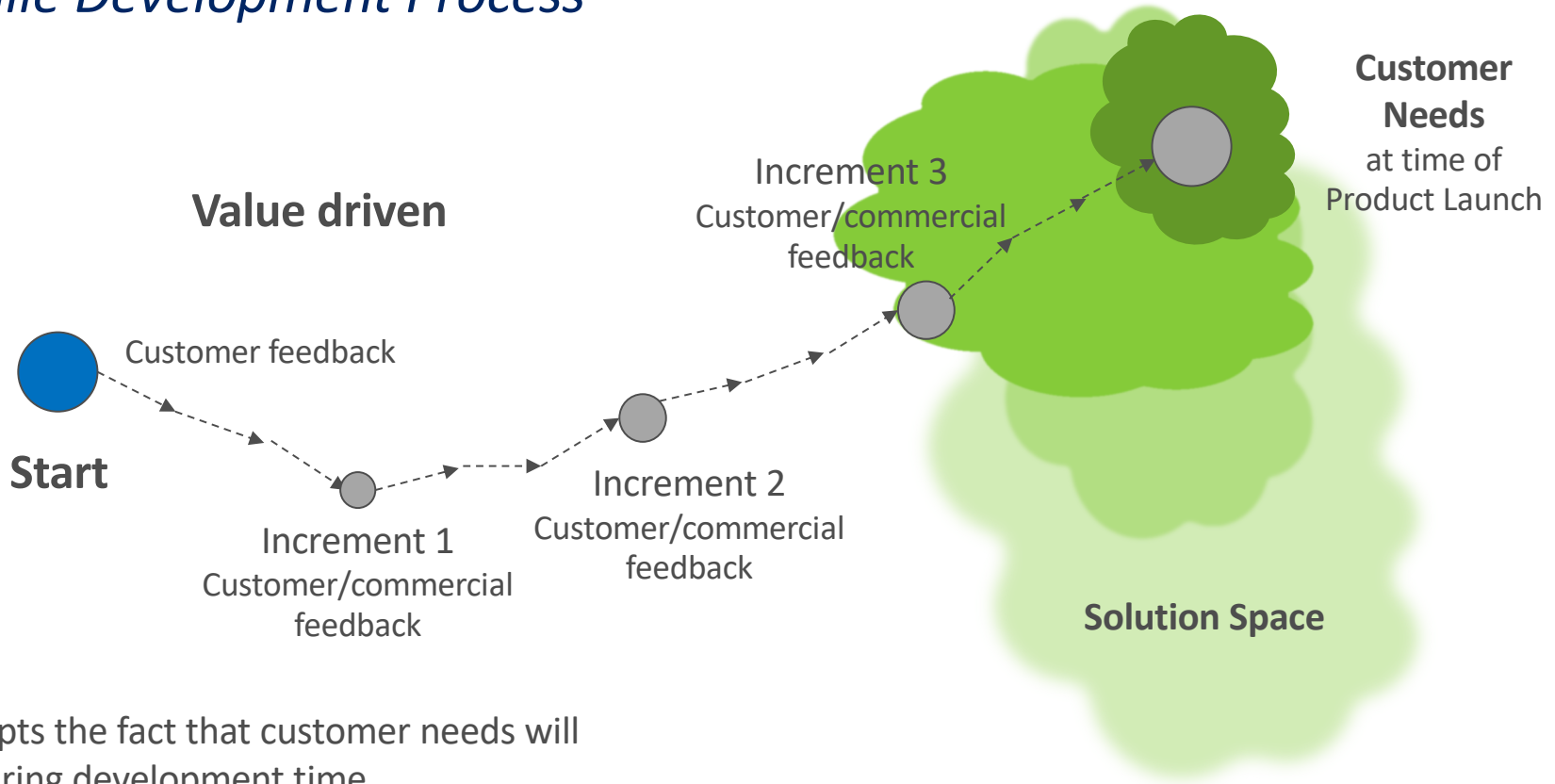
…but what does VUCA mean for Development?

The Agile Development Process



- Agile accepts the fact that customer needs will change during development time
- Changes are normal. Agile harnesses change to achieve competitive advantage
- Requires discipline and fast decision making

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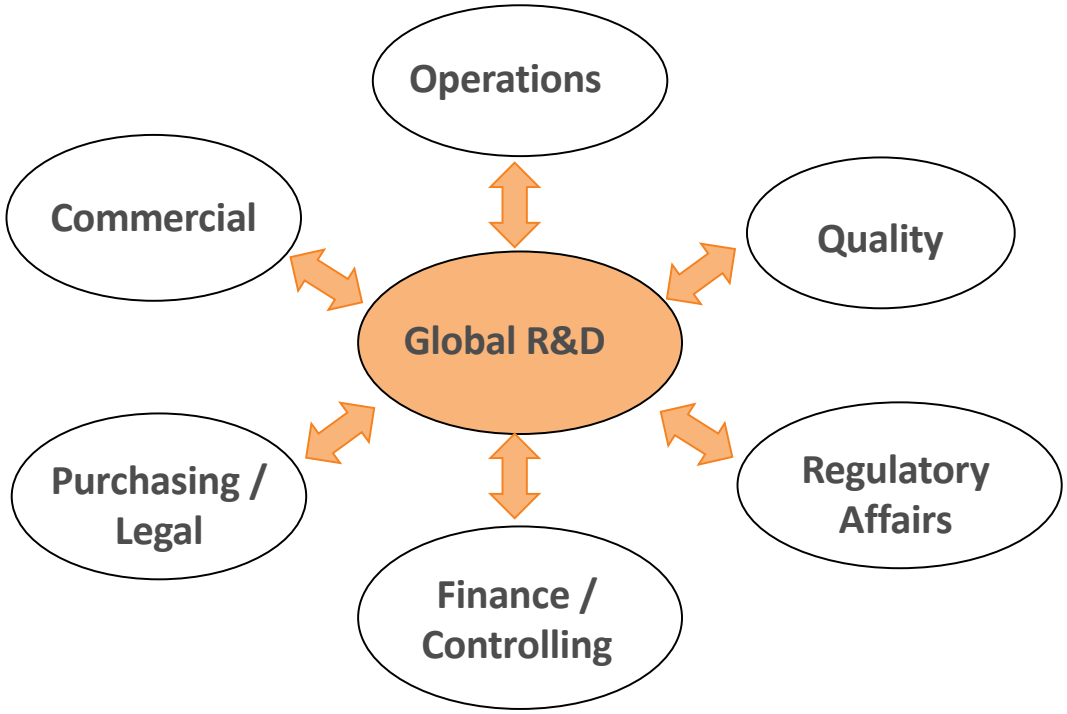
Our Mission



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Our Mission

Implementation of Agile methods (Scrum/Scaled Model) into Diabetes Care R&D in order to enable the successful development of complex products.

Definition of Done:

- Design Control Processes and interfacing processes to other areas are adopted to support Agile *and* Waterfall methods
- Scaling Model is aligned for all sites
- Agile roles are identified and trained and complex projects are running Agile
- Agile mindset has become part of the DC RD&D culture

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Challenges Lead the Way

We have many challenges

- Culture Change
- Continued upper management support
- Different development sites in EU and US, cultures and languages
- Development of complex products, not only SW
- Development of regulated products (IVD and MDD)
- Baggage from previous agile effort – limited to SW and FW

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Challenges Lead the Way

First Agile Attempt

- FW and SW implemented pseudo- Agile
- Software created Agile SOP allowing iterative Agile-like development
- Firmware had SOP in progress, but never completed

Outcome

- No mindset change
- 80%-90% requirements completed prior to start of FW development
- Limited to Firmware/Software other disciplines followed linear approach
- Developed and tested (informal), but *formal* testing at the end
- Implemented ceremonies, but with no change in the way we did work

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Consultant network instead of "One Serves All"

We learned and adapted – built a consultant network

- Each consultant is an expert in a special area
  - Software
  - Hardware
  - Regulated Dev and QMS
  - Change Management
- Native speakers used to alleviate language and cultural differences
- Consistent training provided across the organization

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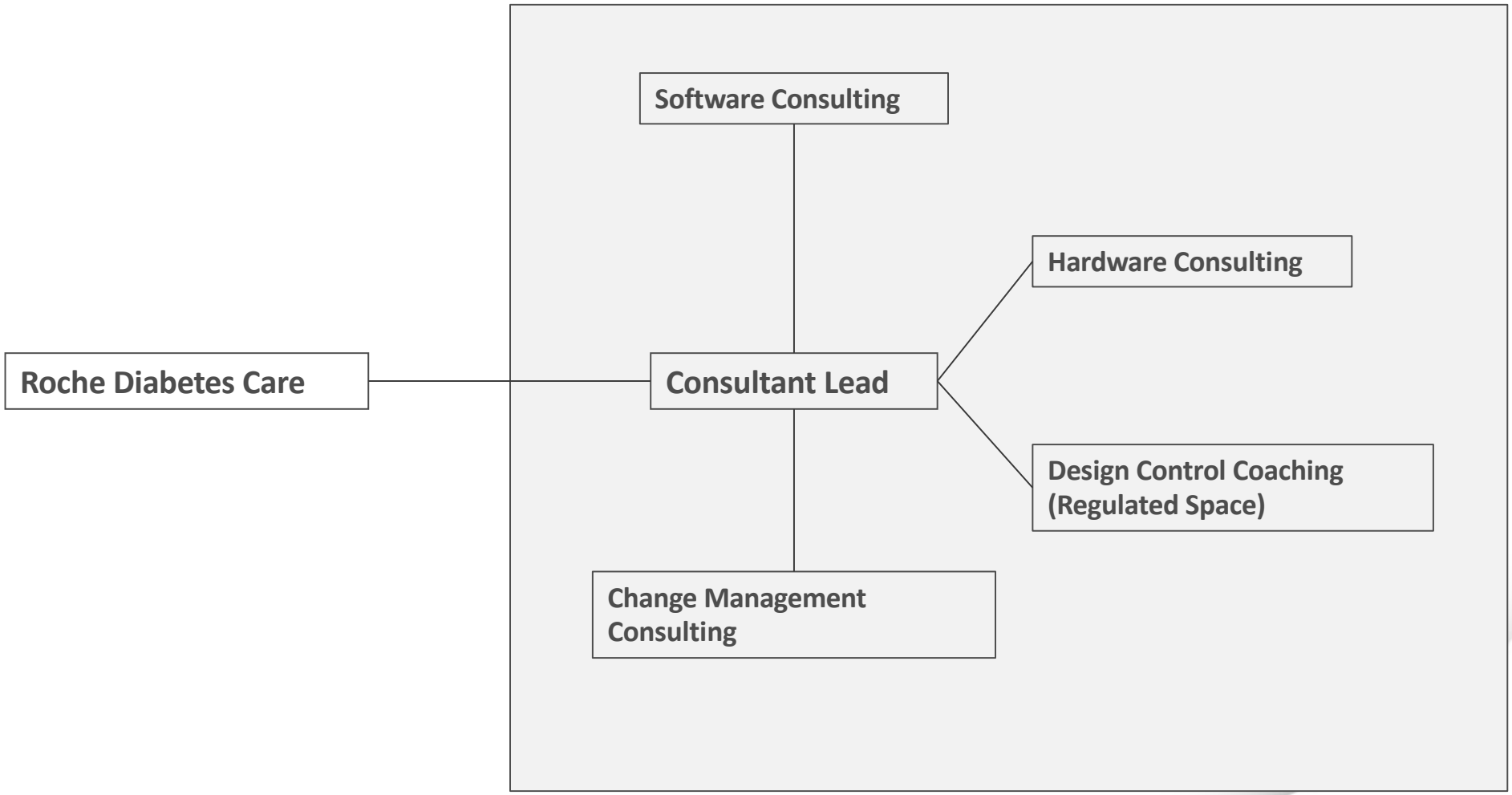
Structure of consultant network



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Successes to Date

SCRUM Pilot Projects

- Single Team projects, start simple and learn SCRUM first
- 6 Pilot Projects started
- Basic Agile/SCRUM training
- 2-3 Workshops
- Intensive coaching for the first 3 months

Design Control Processes

- Harmonization and “Agilization” of Design Control Processes
- Expert consulting: Agile practices in the development of medical devices

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Organizational Preparedness

Change Management and Mobilization

- Stakeholder Analysis and Management
- Change Story
- Change Architecture
- Change Agents – active across the entire organization
- Mobilization Events
  - Fishbowl Events
  - Information events for the entire Diabetes Care organization (>500 participants)
  - Lunch & Learn events
  - Innovation Impulse Forum
- Intranet homepage “The Agile Transition”
- Yammer group “The Agile Transition”

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Organizational Preparedness

Broad Spectrum Trainings

- Basic Agile/SCRUM trainings
  - R&D Leadership Team
  - R&D functional managers
  - Quality Leadership Teams
  - Procurement Leadership Team
- Use of Agile methods in the development of MD
  - Process Owners
  - Quality functions
  - Pilot Teams
- Agile workshops with R&D and Quality departments
- SAFe Training

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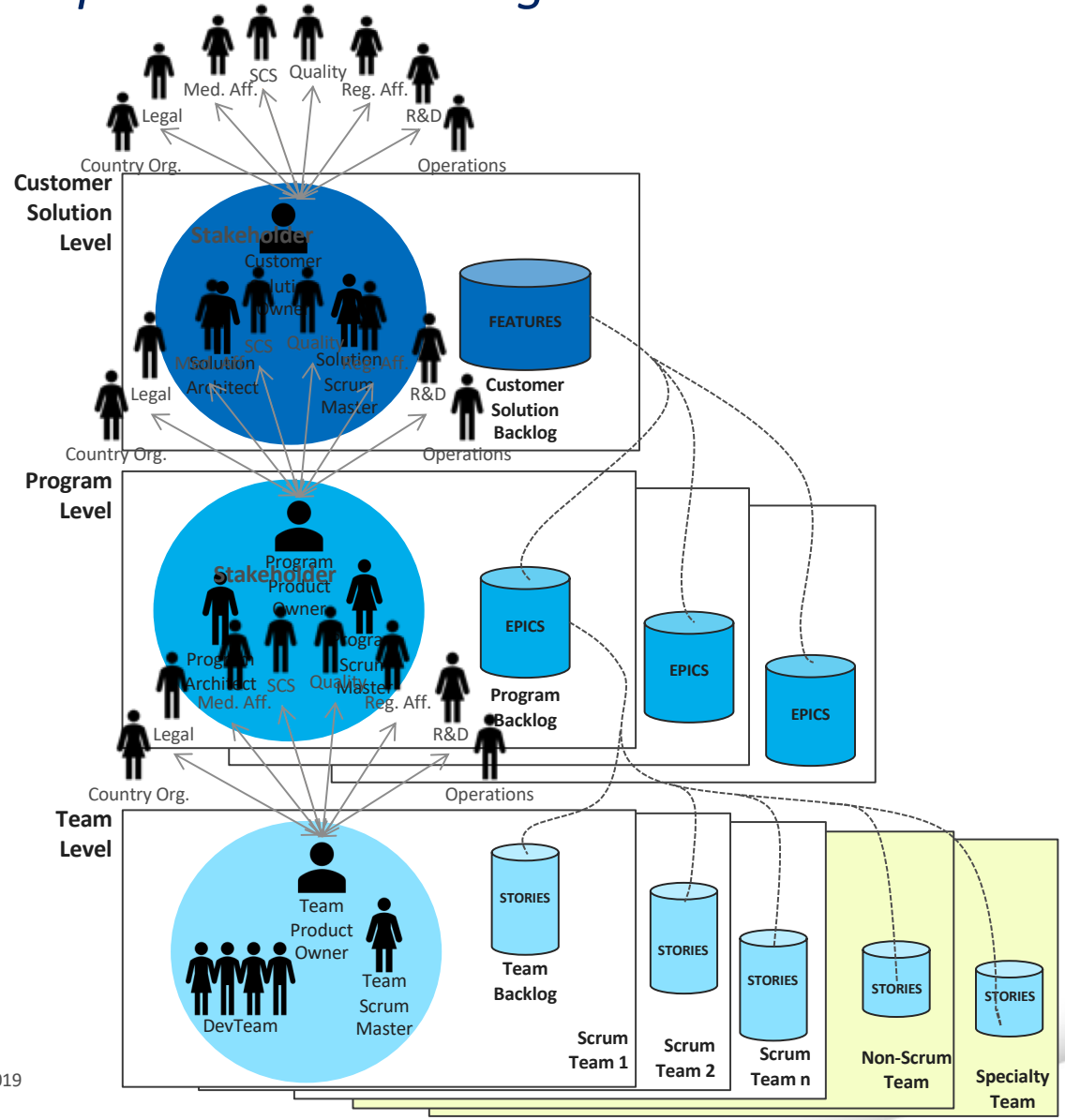
Organizational Preparedness – Scaling the model



Shared Services

- Quality
- Regulatory
- Medical Affairs
- Human Factors
- Biocompatibility
- External suppliers
- System Integration
- Etc.

➔ Visitors (help team members to complete tasks)

➔ Part time members (commits to the story on Sprint Planning

➔ Specialty Team (get and commit to Backlog items)

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Organizational Preparedness

Role of Program Architect (System Engineer)

- Plans and develops Architectural Runway for new Features and Epics
- Establishes critical Nonfunctional Requirements (with the PO's)
- Collaborates with business stakeholders in defining the technology infrastructure
- Defines subsystems and their interfaces, allocates responsibilities to subsystems
- Defines, explores, and supports the implementation of solution Enablers
- Support PO's in the decomposition and allocation of the Program Backlog
- Provides architectural guidance and oversight to the Teams

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Where are we in our journey

No transformation of this magnitude happens overnight

- Internal team was established Q4 2017 and gained traction Q1 2018
  - Supporting consultant network established early Q1 2018
  - Process changes initiated Q1 2018
- Change Management has dedicated team as part of the overall transition team
- Expectation set with management was 2- 3 years to affect a change
- Responsibilities transition fully to internal resources
  - Coaching
  - Training

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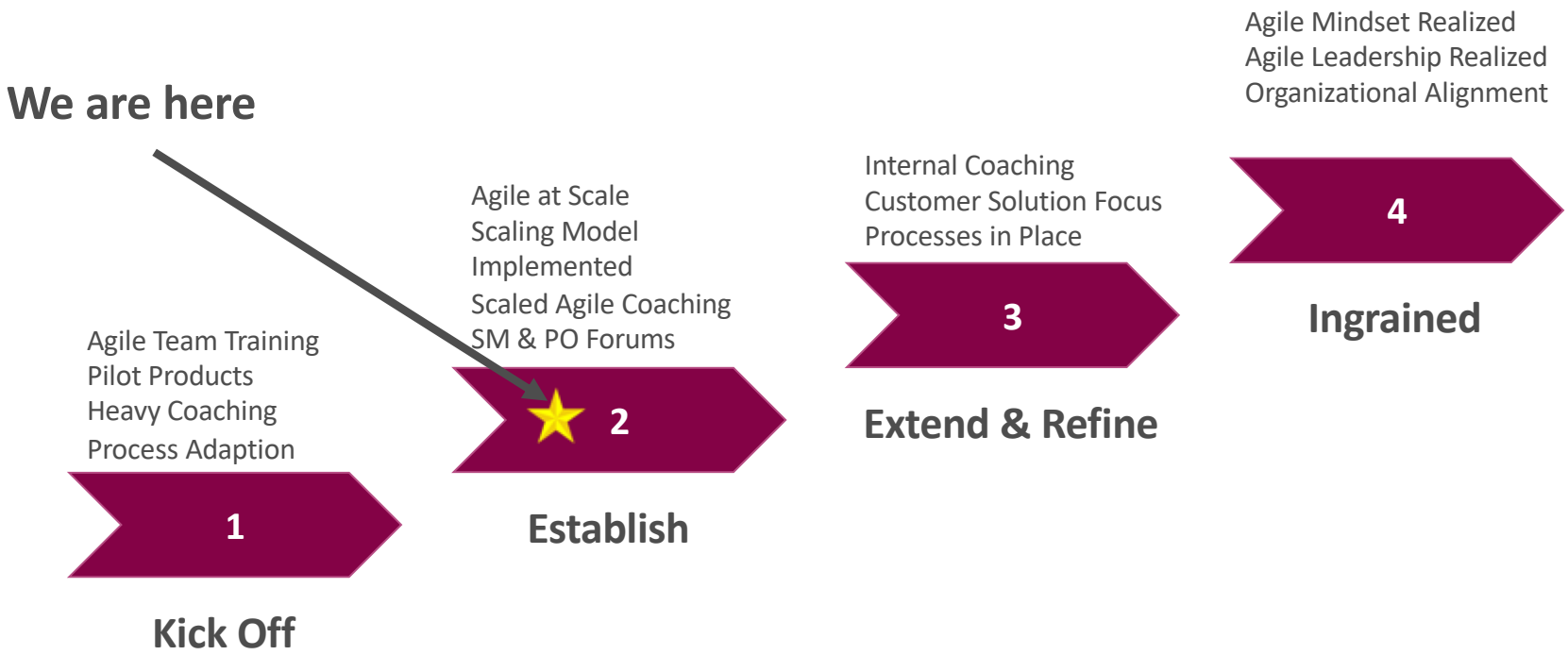
Agile State of Mind

Where are we in our journey



Agile Mindset Growth

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Challenges so far…

Roche

- Product Owner not fully empowered as the single point of responsibility
- Lack of dedicated Development Team members – still *multi-tasking*
- Minimal Viable Product concept not fully accepted
- Pilot projects working within the existing QMS
  - In addition to being an Agile Pilot Project, teams have to work within existing Design Control Process that does not yet fully support Agile

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Next Steps

Continue with ongoing activities

- Training and coaching Pilot Teams (existing and new)
- Additional trainings
- Mobilization events

New activities

- Implementing and refining Scaled Agile Framework
- Broaden the scope of our activities from R&D to other business areas (Commercial, Operations, Quality, Procurement, etc.)
- Agile leadership workshops
- Process and decision criteria for Waterfall vs. Scrum
- Initiate & support broad usage of Agile methods beyond Scrum within projects and R&D organization

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The Agile Transition

Key Take-Aways

- Difficult – culture change…
- Upper Management support
- Expert level guidance – do not try this at home
- It’s hard to change a culture which had success in the past

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Thank you for attending!

Share your experiences at #HWGSEC