



CDISC Implementation Trends

PhUSE SDE Copenhagen, 15 June 2016

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CDISC implementation drivers

Two waves of CDISC implementations

First wave

- Compliance driven implementations focusing on delivering CDISC compliant data
 - None or limited benefit realization
 - Increasing effort and resource demand
 - License to operate implementations



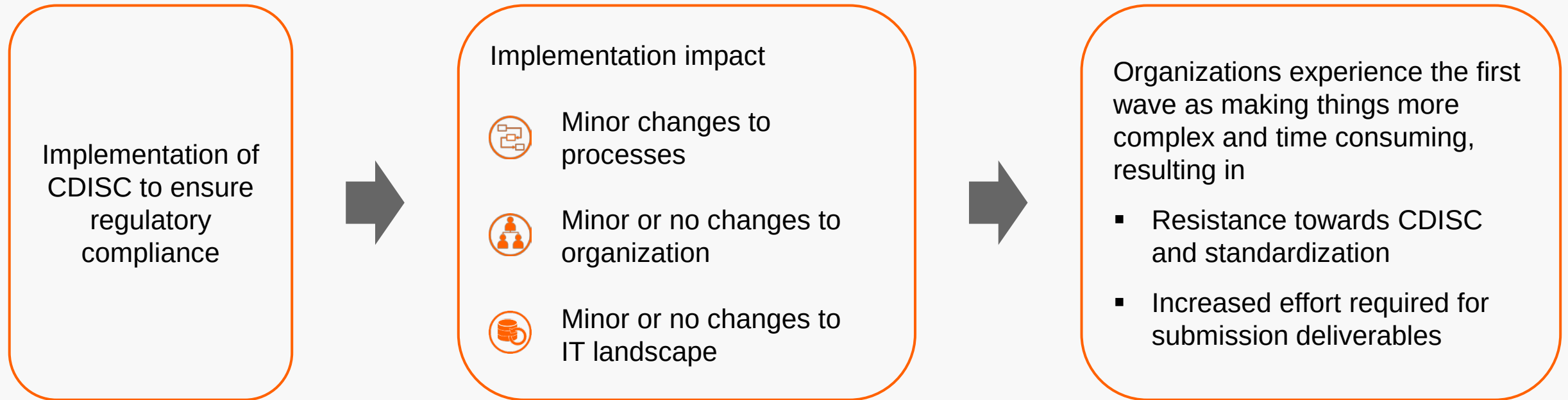
Second wave

- Optimization driven implementations focusing on how CDISC can improve speed and efficiency
 - Identifying standardization benefits
 - Increased benefits due to standardization across the industry
 - Benefit realization expected



First wave of CDISC implementations

Business as usual plus a little more



First wave of CDISC implementations

Implementation examples

Process

- Process changes within trial execution, analysis, and reporting to support, e.g.
 - Governance and maintenance of CDISC standards
 - Use of controlled terminology
 - Delivery of SDTM, ADaM and define.xml



Organization

- Organizational changes to support new processes, e.g.
 - Establish or expand data standards departments
 - Use of external expertise



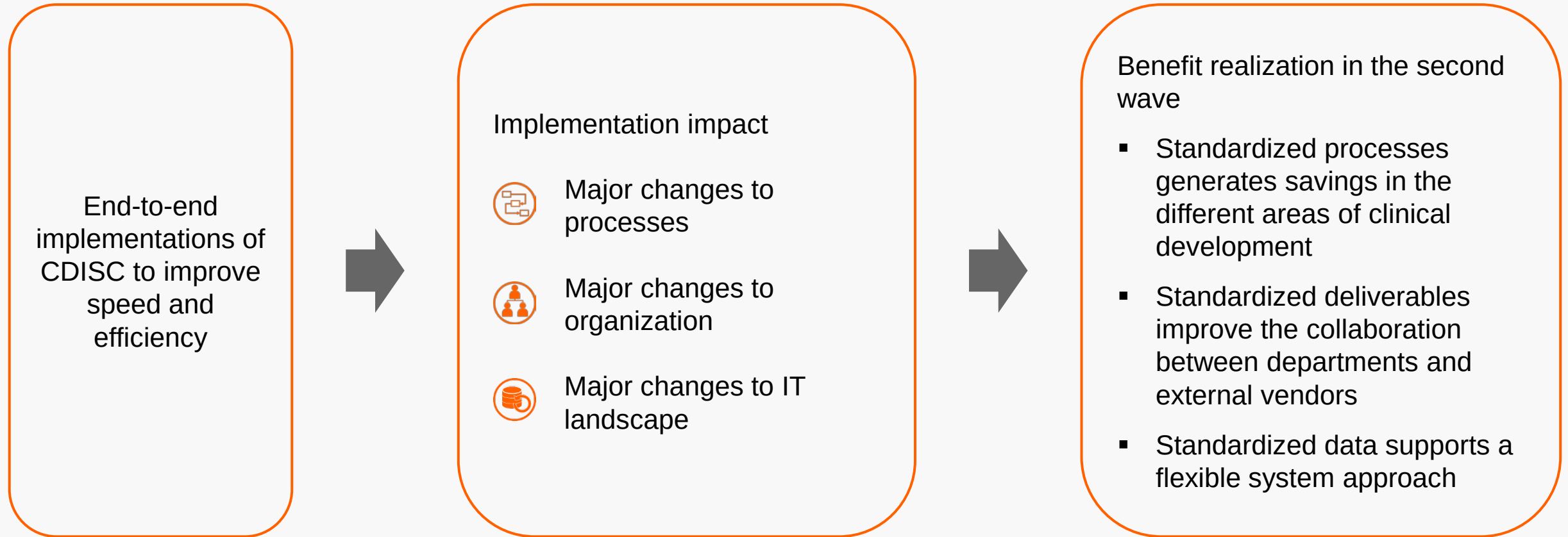
IT

- Process changes driving IT improvements, e.g.
 - Metadata management to support control of standards
 - CRF development and data collection to support controlled terminology and SDTM
 - Analysis programming to support use of ADaM



Second wave of CDISC implementations

Process optimization and IT implementations



Second wave of CDISC implementations

Implementation examples

Process

- Extensive process improvements within clinical development to support, e.g.
 - Metadata driven trial setup
 - Risk based monitoring
 - Data visualization and reporting



Organization

- Organizational changes to support, e.g.
 - Cross-functional collaboration
 - Functional outsourcing



IT

- IT changes to support new processes and organizational needs, e.g.
 - Implementation or improvement of core systems
 - Increased use of integrations with external systems



CDISC implementation challenges

Before we can harvest the benefits of CDISC

Change management

- New terminology and standards
- New skills
- Limited creativity



IT challenges

- Version control
- Metadata management
- Immature solutions



Key takeaways

What can we learn from the CDISC implementation trends?

- Understand the nature of the CDISC implementation in your company
 - Proactivity towards implementation challenges
 - Ease transition after implementation

- Accept the evolutionary approach of CDISC implementations
 - Not feasible to implement all aspects of CDISC at once
 - Vendor solutions must support the evolutionary approach

- Remember that CDISC does not solve all problems – new challenges arise
 - Focus on the challenges in process design, organizational structure, and IT implementation
 - Standardization projects continue after ensuring regulatory compliance

Questions?

