

Regulatory Modernization

State of the Industry and MedTech Leader Perspectives

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Vision

Building the Industry Cloud for Life Sciences

Values

Do the Right Thing

Customer Success

Employee Success

Speed



A Public Benefit Corporation

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Regulatory Pulse Benchmark Study

Scope



Global Compliance



Global 24/7 Visibility



Speed to Market



Post-Market Compliance



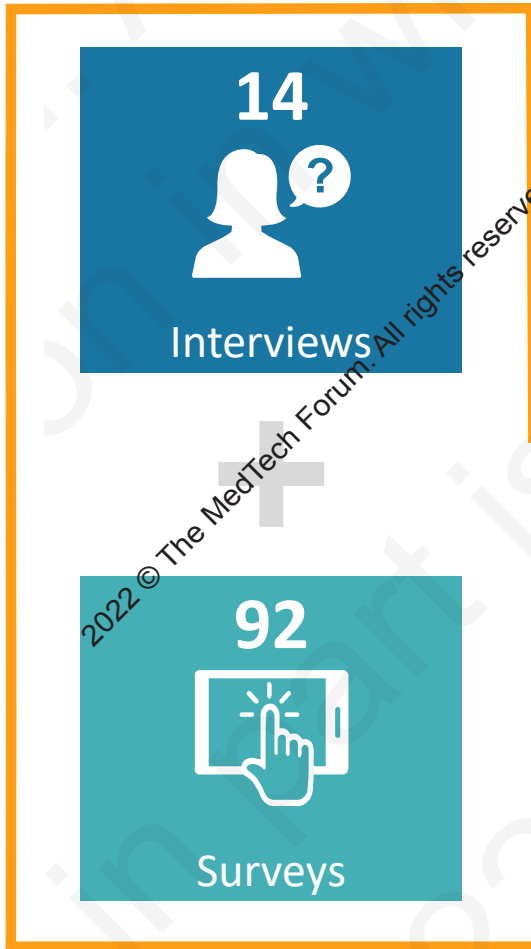
Regulatory Modernization

MEDTECH INDUSTRY'S PROGRESS TOWARDS MODERNIZING REGULATORY OPERATIONS

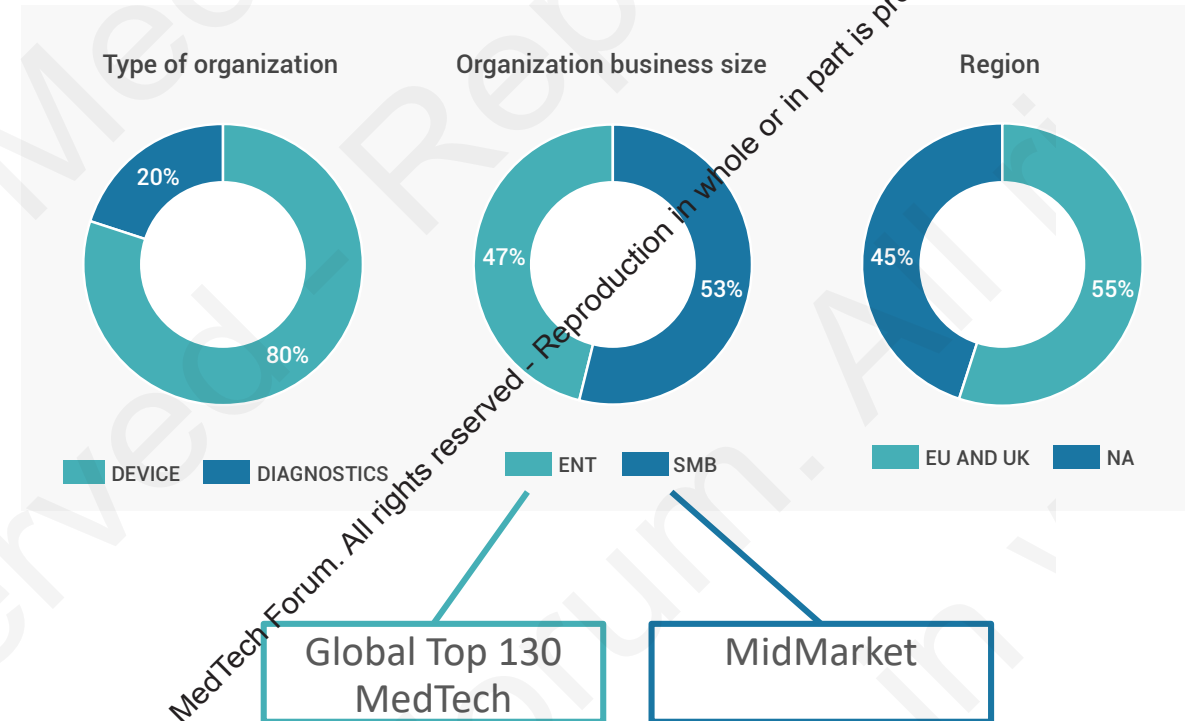


Regulatory Pulse Benchmark Study

Respondents & Demographics



100+
RA Professionals*



*Representing 90 companies

Regulatory Pulse Benchmark Study

Value for the Industry

Focus on MedTech



Competitive Insights

Peer-to-peer MedTech comparisons, current state & future needs.

Focus on Internal RA Organization



Bottom Line Efficiency

Direct influence on the performance of the internal organization (vs external indirect influence).

Focus on Regulatory Transformation



Top Line Revenue

Enable RA as contributor to company performance and speed to market, rather than cost center.

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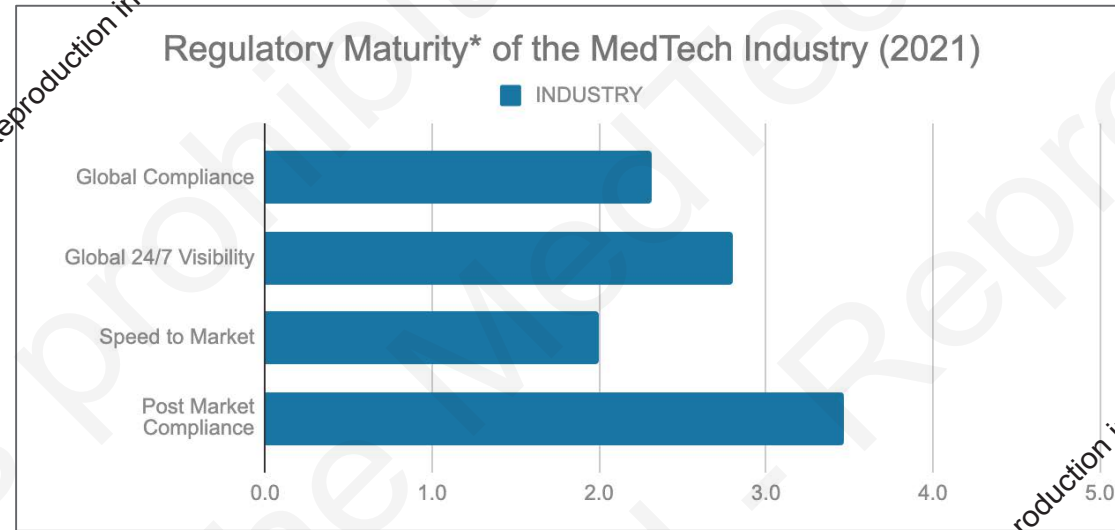


Findings

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Regulatory Maturity* of the MedTech Industry

2021 State of the Industry



Below Average Maturity

Global compliance, global 24/7 visibility and speed to market

- Growth through M&A without integration
- No “need” for cross-functional collaboration
- Value of data undervalued/ underestimated
- Regulatory as “black box” for other functions

Above Average Maturity

Post Market Compliance

- Historic scrutiny from regulatory authorities

* Maturity regarding unified and connected technology adoption to drive top-line and bottom-line performance and reduce compliance risks



Key Take Aways

Why Should you Care?

Top Line Revenue

- The faster the submission compilation, the higher the speed to market, the faster revenue comes in
- Missing revenue due to expired registrations
- Not gaining full potential from M&A portfolio increase

Compliance Risks

- Unannounced audits pose significant risks
- Data inconsistency leading to overlooked signals or trends
- Data driven decision making based on weak data
- Mismatched claims across regions

69%

of surveyed
MedTech **don't**
have a global RIM
system in place

Bottom Line Efficiency

- Wasted efforts searching, duplicating, verifying (cross-functional) data and version control
- Wasting time on reporting based on weak data
- M&A bottom line impact of contractors etc. to revise unscalable processes

Knowledge Vulnerability

- When people leave, knowledge leaves
Employee retention rate: highly educated RA staff executing admin tasks
- Talent Attraction



Global Compliance

Submission Management - Value for the Industry

Submission documents management

> 66%

Local laptops, file shares, or regional document management systems

Submission forecast, planning and tracking

76%

Individual or manual tracking **spreadsheets**

Submission document review, approval and publishing

40%

Done individually via **email** without a content system in place.

Health Authority commitments

50%

Received and managed via **emails** or **multiple logs**.

Bottom Line Efficiency

Significant (wasted) efforts searching, duplication, verifying data

Compliance Risk

- Version control, consistency of content, audit trail, low audit readiness
- Unannounced audits pose significant risks
- Mismatched claims across regions

Knowledge Vulnerability

- When people leave, knowledge leaves.
- Employee retention rate.
- Talent attraction

Top Line Revenue

The faster the submission compilation, the higher the speed to market, the faster revenue comes in.





Global 24/7
Visibility

Global 24/7 Visibility

Registration Management - Value for the Industry

Global registrations
governance & tracking

60%

Uses a **single system**

Global registrations
data collection

32%

Experiences
inconsistent data

Performance and KPI
reports

55%

Creates reports
manually.

Bottom Line Efficiency

Wasting time on reporting based on weak data.

Compliance Risk

- No line-of-sight risks sales to position products on non-registered markets
- Mismatched claims across regions

Impactful Decision Making

- Line of sight = competitive advantage. Data driven decision making for senior leaders (where do you spend your time on?).

Top Line Revenue

Missing revenue due to expired registrations.





Speed to Market

Speed to Market

Scalability & Flexibility - Value for the Industry

Regulatory submissions

63%

managed with **manual processes**

Regulatory processes

79%

manually revised when the organization grows.

Bottom Line Efficiency

- M&A bottom line impact of contractors etc. to revise processes.
- Labor intense

Top Line Revenue

- Rework & remediation when local regs aren't met from start → perceived as hurdle to market
→ low speed to market = late revenue
- Not gaining full potential from M&A portfolio increase





Post Market Surveillance

Quality & Regulatory Interdependencies - Value for the Industry

End-to-end complaints
handling process

74%

Managed with a
**centralized log or
system**

Trending PMS data

64%

Inconsistent data
experienced

Change control process
across quality and
regulatory departments

59%

partly integrated
or completely
automated.

Bottom Line Efficiency

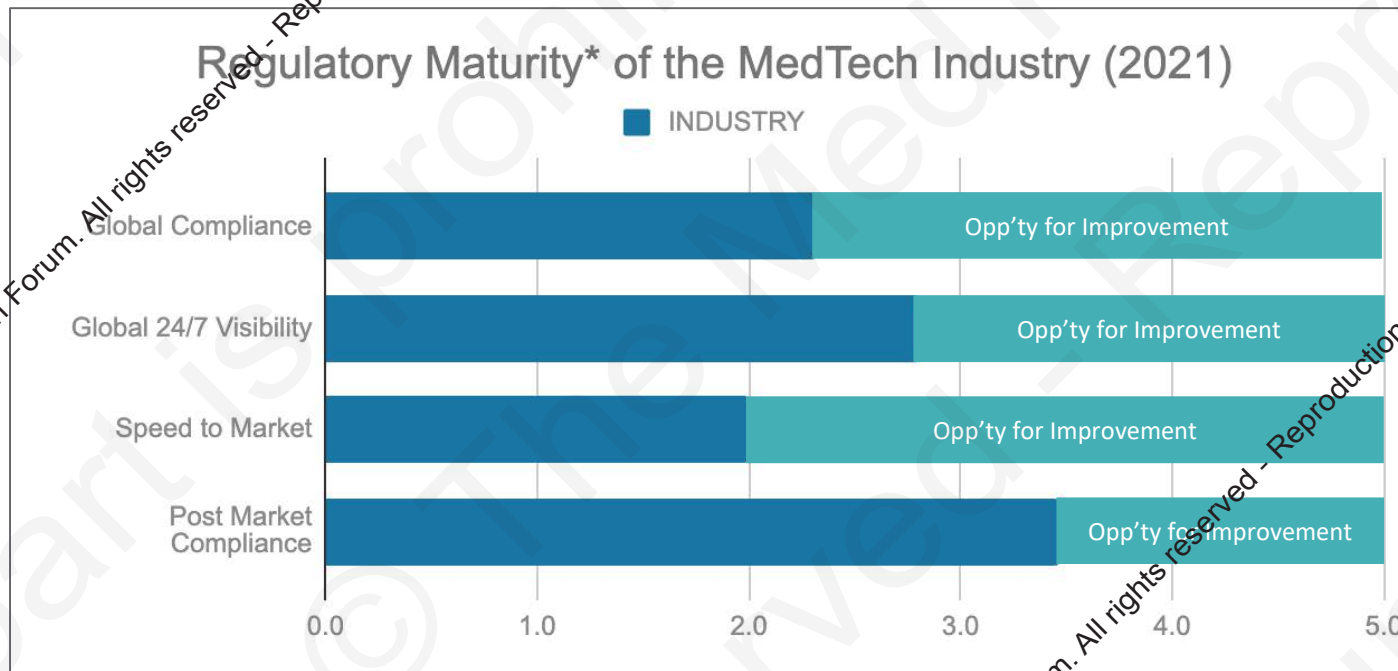
- Very intense and lengthy process, any improvement supports the bottom line.
- Lack of well integrated cross—functional systems poses a burden on the bottom line

Compliance Risk

- Efficiency for compliance due to reduced reporting timelines under MDR and IVDR.
- Data inconsistency leading to false negatives/ overlooked signals or trends

Regulatory Maturity of the MedTech Industry

Improvement Opportunity



* Maturity regarding unified and connected technology adoption to drive top-line and bottom-line performance and reduce compliance risks

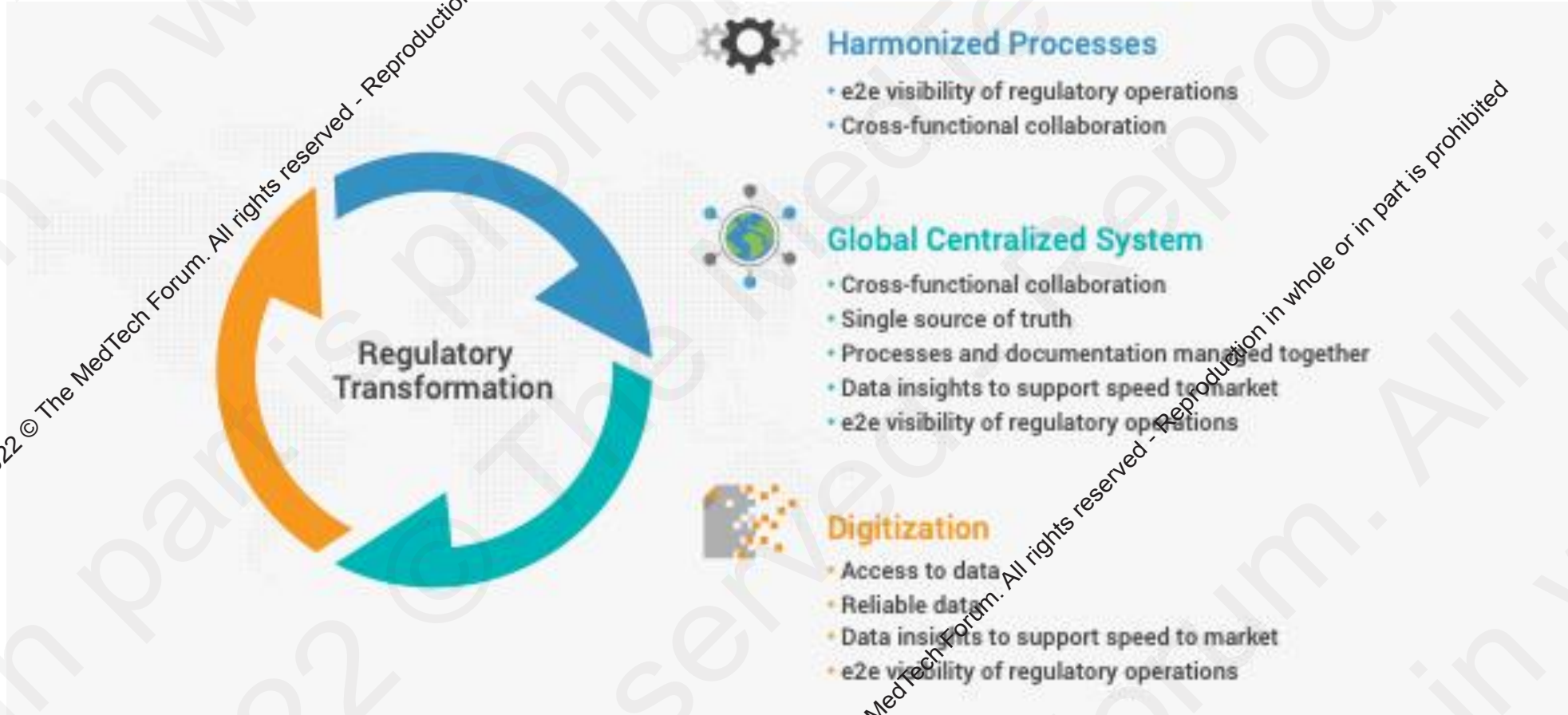




Regulatory
Modernization

Regulatory Transformation

Industry's Regulatory Vision of the Future



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Continuous change as a driver for transformation

Realizing the Vision of the Future

Distraction

- Short Term Vision
- Reactive Approach
- Technology to support short term objectives

Industry Dynamics

Driver for Transformation

- Long Term Strategy
- Proactive Approach
- Technology to enable real-time insight

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An Opportunity for Regulatory Transformation

What drives change for MedTech companies?



Lack of Global
Visibility and Accountability



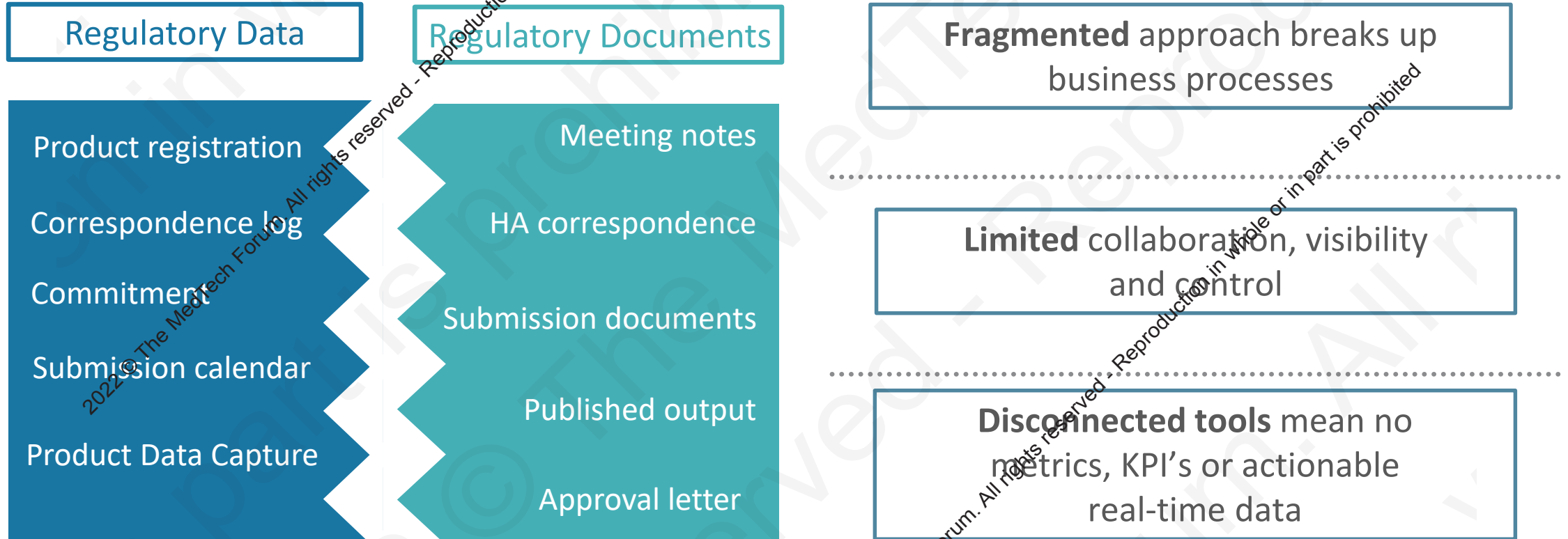
Inability to Report on
Real-Time Data



Inefficient and
Outdated Technology

Regulatory Operations Span Data and Documents

Understanding a Disconnected Landscape



Regulatory teams cannot meet the demands of complex, changing regulations



Unified RIM Benefits



Reduce RIM Systems and Tools



- Real-time access to product application history / chronology
- Less IT maintenance
- Higher data quality



Reduce Integrations and Handoffs



- Establish one source of the truth for regulatory data and docs
- Decrease time and cost for custom dev and validation



Reduce Manual Tracking



- Enable real-time access and collaboration for all activities
- Accelerate the end-to-end submission process

Key Take Aways

Why Should you Care?

Impact

Need

Top Line Revenue

Bottom Line Efficiency

Compliance Risks

Knowledge Management

69%

of surveyed
MedTech **don't**
have a global RIM
system in place

Global Centralized System

Harmonized Processes

Digitization

Proactive Approach

Technology as an Enabler

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