The Predictability Premium

BUILDING STABLE GROUND FOR REMS

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Outline

- Current Regulatory Environment
- RIC's Role in Policy Development
- Proposed Examples
- Case Studies
- Discussion

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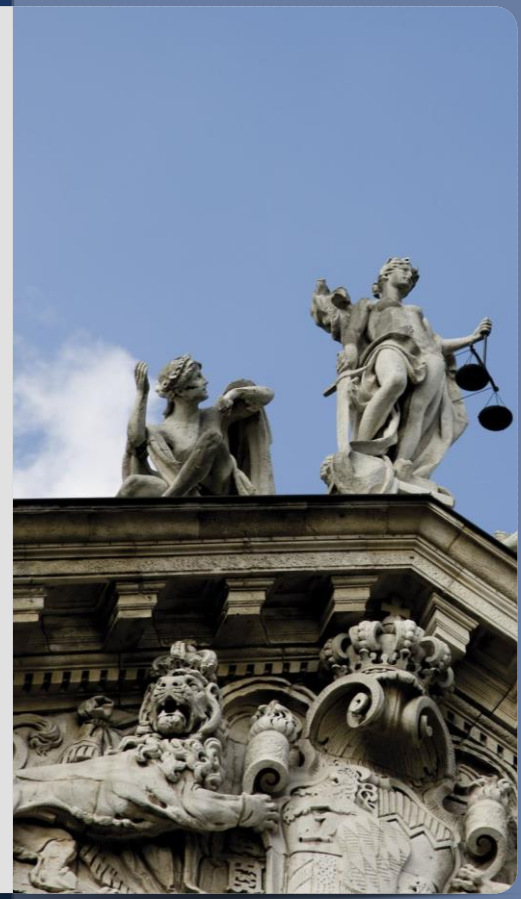
Current Regulatory Environment



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Current Regulatory Environment

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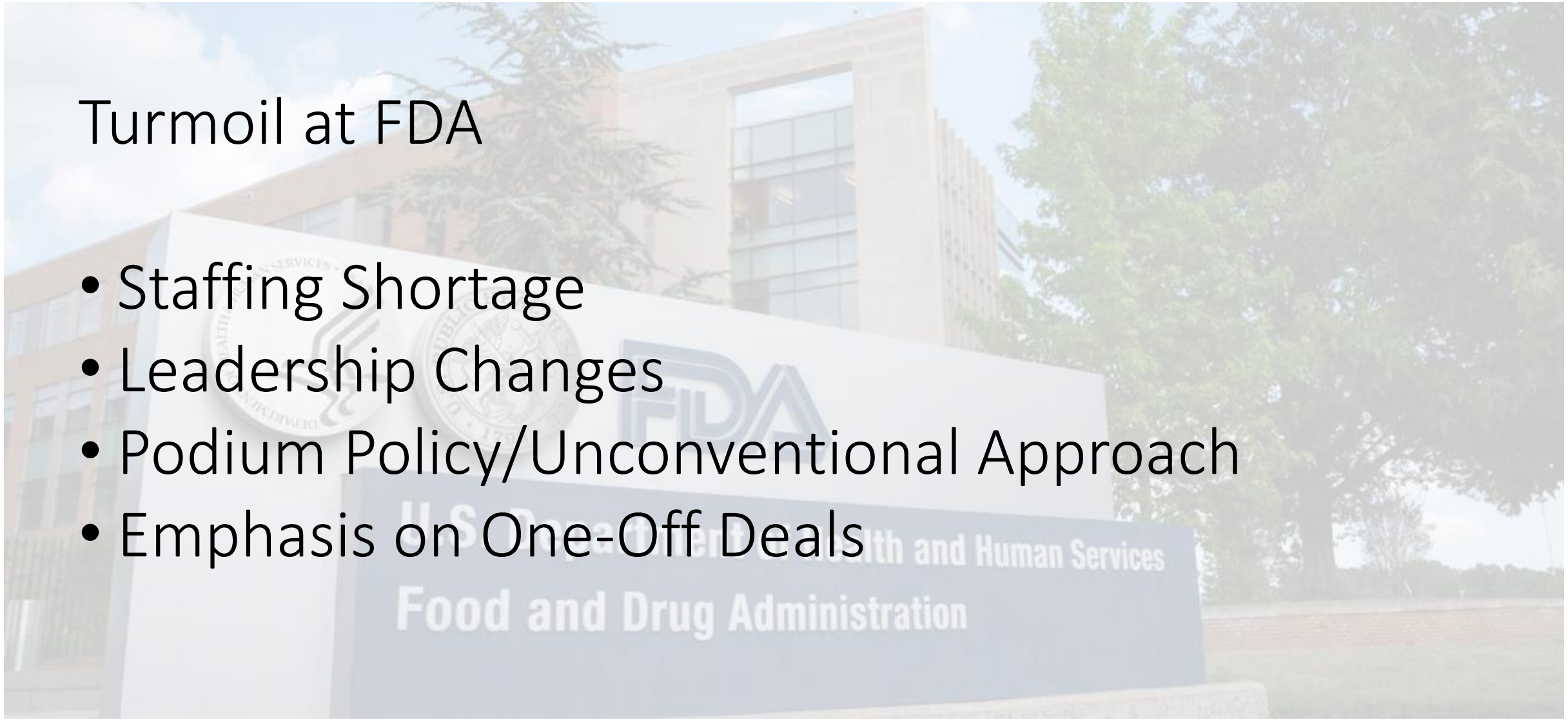


Turmoil at FDA

- Staffing Shortage
- Leadership Changes
- Podium Policy/Unconventional Approach
- Emphasis on One-Off Deals

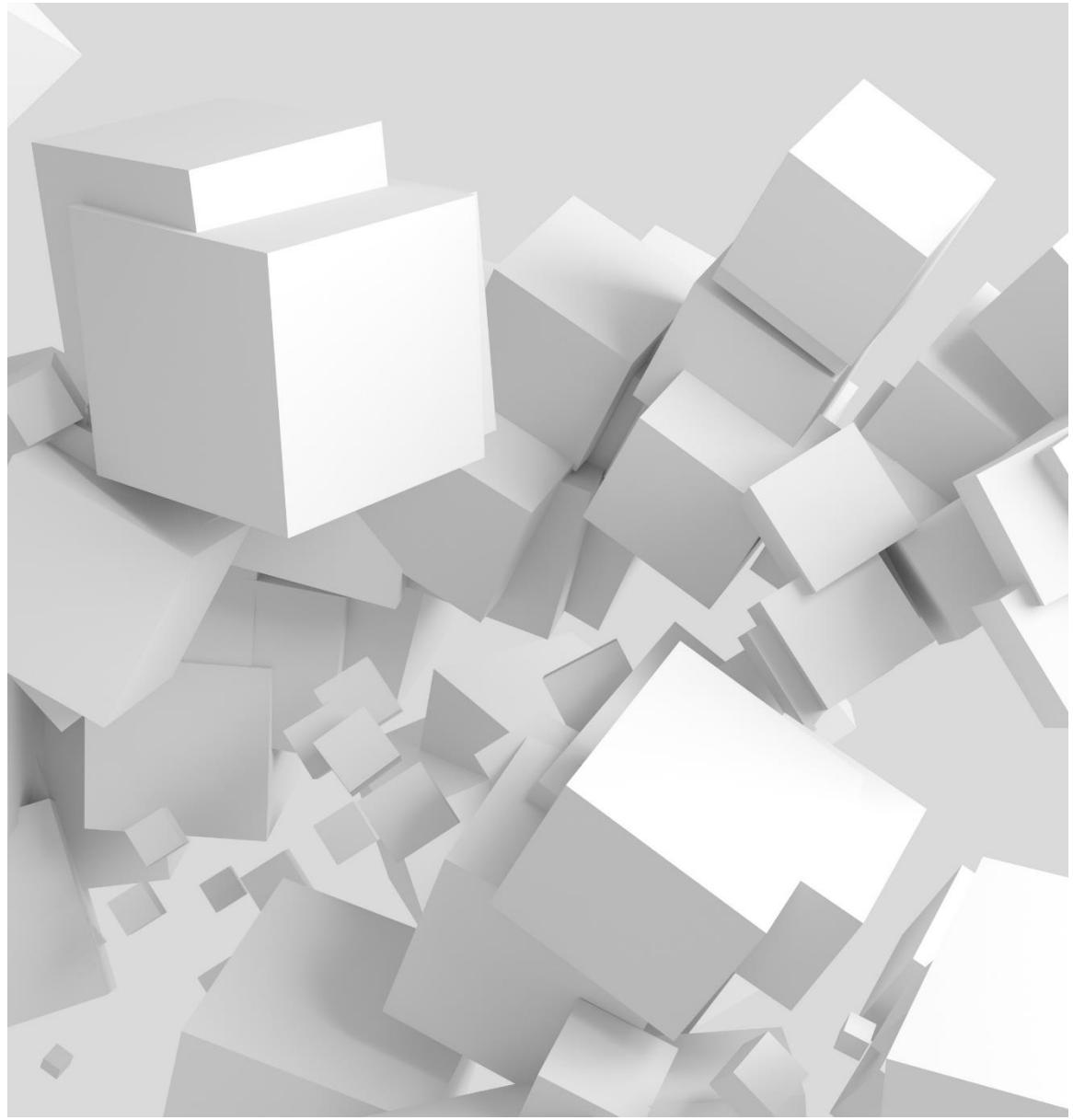
Why Stability Matters

Consistency

Rely on prior positions when designing programs

Predictability

Reduce risk of late-stage requirement shifts



REMS Impact

Uncertainty Hits Close to Home

- Staffing shortages might mean longer timelines, inconsistent feedback
- Increased political influence – will use of REMS authority expand?
- Leadership willingness to stretch legal authority

The Ongoing Uncertainty Struggle

Industry Challenges

- Submission delays for unknown reasons
- Not knowing whether Agency will accept new idea
- Fear that small changes might trigger larger modification

Agency Reality

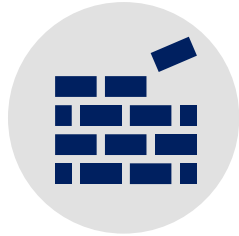
- Proposals have cross-program implications
- Precedent concerns
- Novel legal complexities

RIC can counter uncertainty with policy strategy

Laying a foundation for the long term

Collaborate, Standardize, Innovate to Modernize REMS

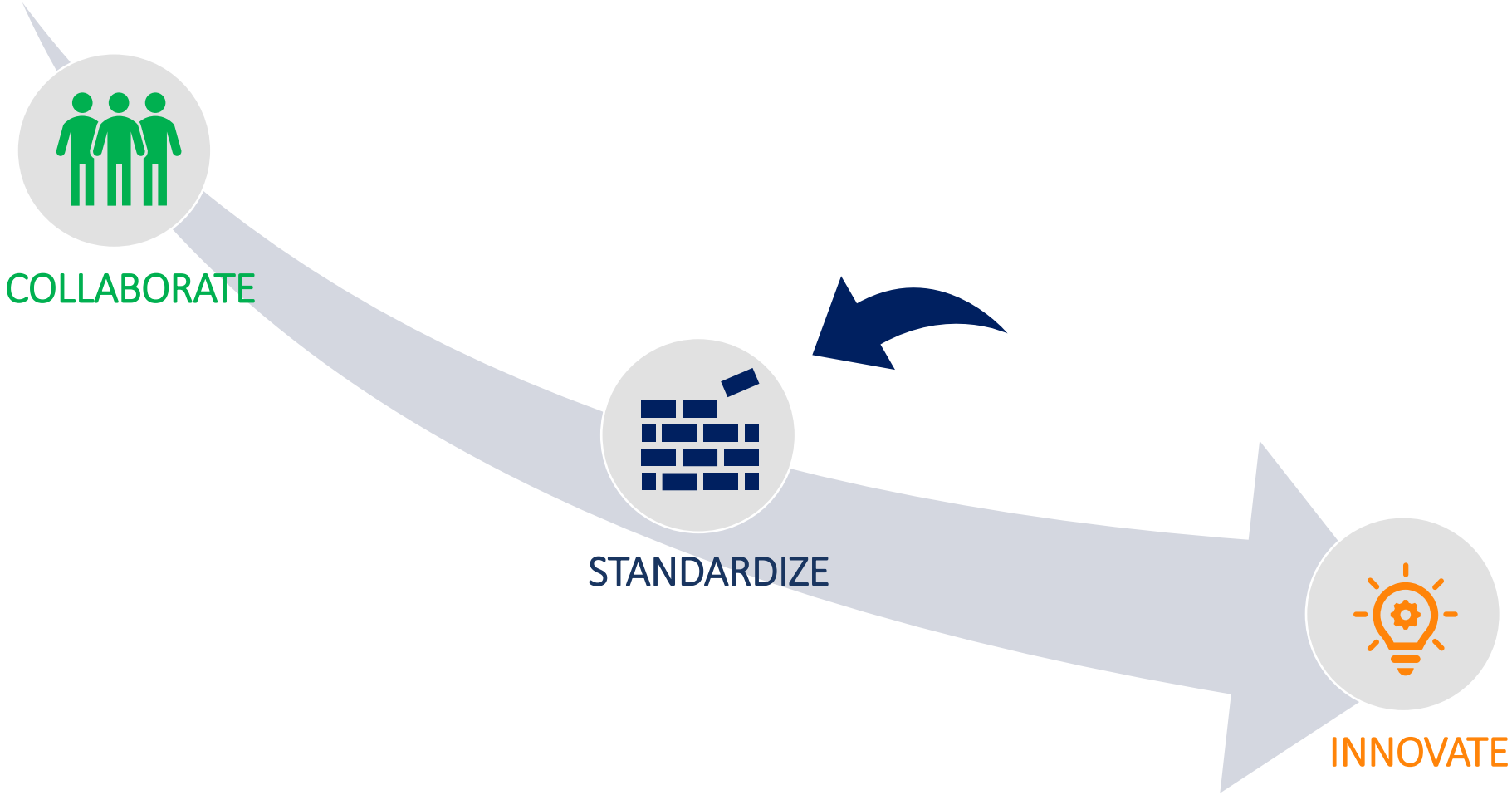
COLLABORATE



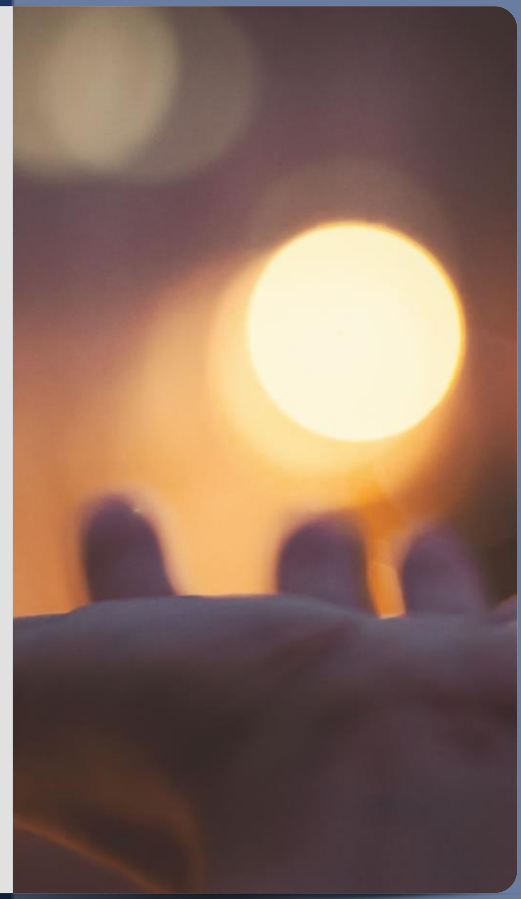
STANDARDIZE

INNOVATE

Collaborate, Standardize, Innovate to Modernize REMS



Examples



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Example #1:
Sharing Innovation Successes

Assessment shows risk was successfully managed through a particular physician training method

You share method with others, and they use that info to improve their own program

These successes persuade FDA to adopt more standardized approach to prescriber training for a particular type of risk

Time spent on tech solutions instead of back-and-forth with FDA

Innovative tech solutions benefit entire industry

Example #2:
Engagement with Stakeholders in Health Care System

ENGAGE

Meet with pharmacy and physician groups, gather info, workshop solutions

ANALYZE

Discover how requirements are implemented in real world, implications for different practice settings, etc.

EDUCATE

How certain distribution models will be used, etc.

SET EXPECTATIONS

FDA and industry have shared understanding and fewer surprises

Example #3
Tech Advancement in REMS

Review FDA's General AI Guidance and extrapolate to REMS context

Develop consensus on use cases, specific tools, and validation methods

Present AI REMS capabilities to FDA as united voice

Example #4

Explore Legislative Solutions both Agency and Industry can Support

Data Standards

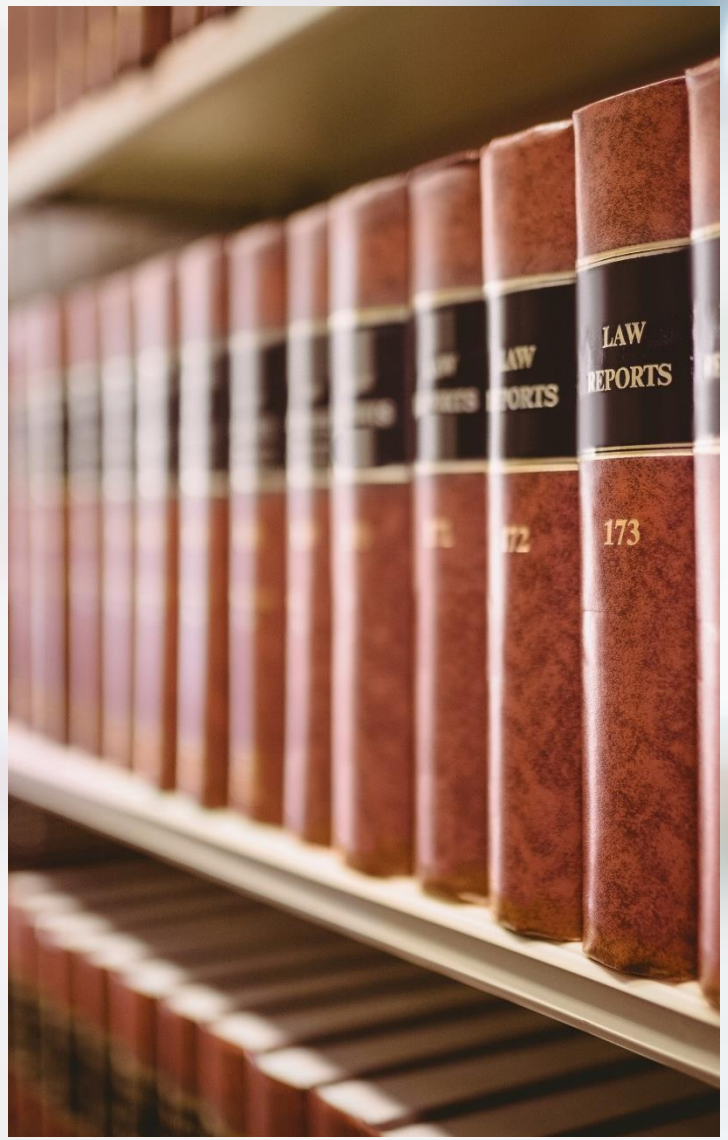
FDA can require use of established data standards

More Specificity in Requirements

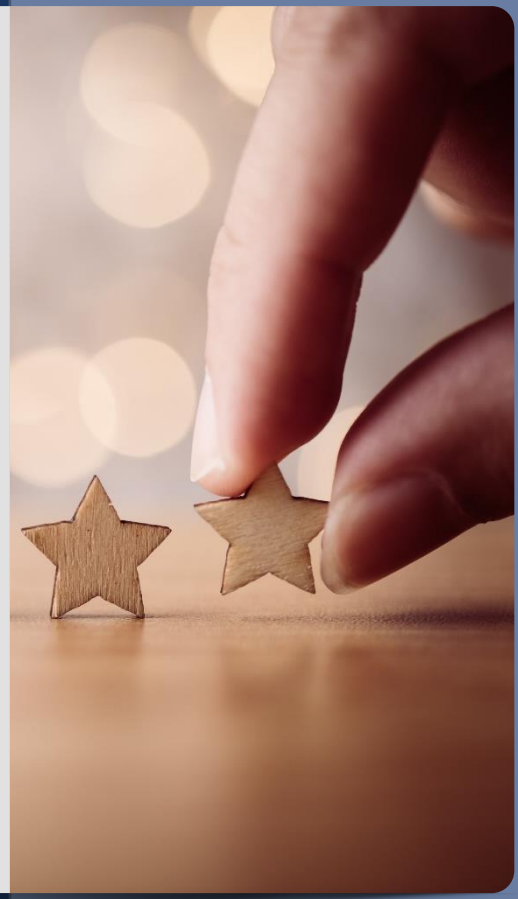
FDA can be more proscriptive, and industry has clearer expectations

Pilots

For things like mobile apps and smart devices



Case Studies



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Case Study:
Seeking Standardization for Patient-Reported Outcomes

Before FDA guidance, acceptance of PRO was highly variable.

Industry advocacy through trade group sought:

- Clear evidentiary criteria
- Predictable expectations
- Early engagement pathways

Resulting guidance is strict, but provides written standards, common language, and transparency

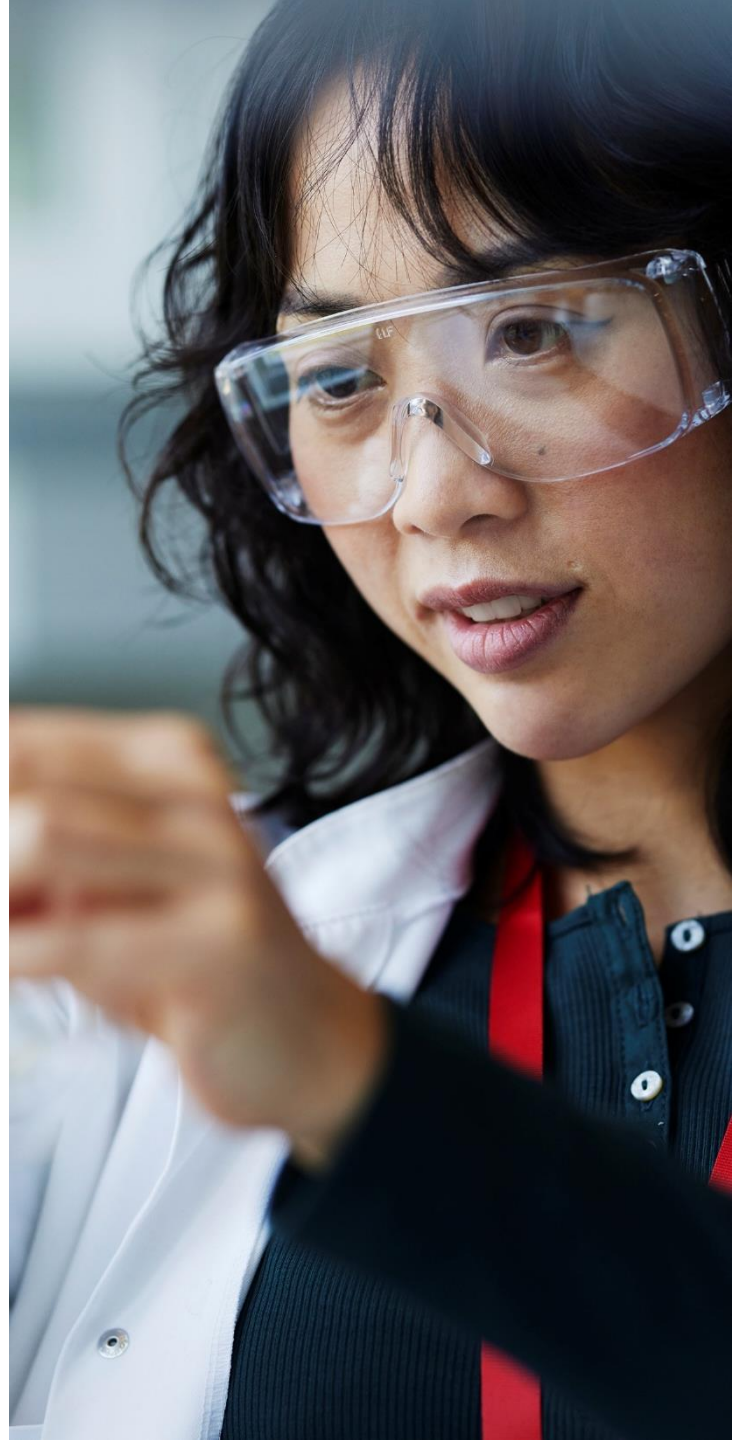
Case Study:
Learning from Drug Shortages

FDA had assumptions about manufacturing:

- Commercial scale similar to clinical scale
- Tight control over post-approval changes does not affect supply

Meetings following drug shortages educated FDA:

- Process must evolve as scale increases
- Freezing manufacturing processes early leads to fragility
- Global supply chains don’t behave like single-site models



Guiding Principles Behind These Examples

Bringing requests as system-level problems, not product-specific exceptions

Asking for standards, not leniency

Showing you understand FDA's internal constraints

Educating the Agency

Collaborate

Invest time into broad policy solutions

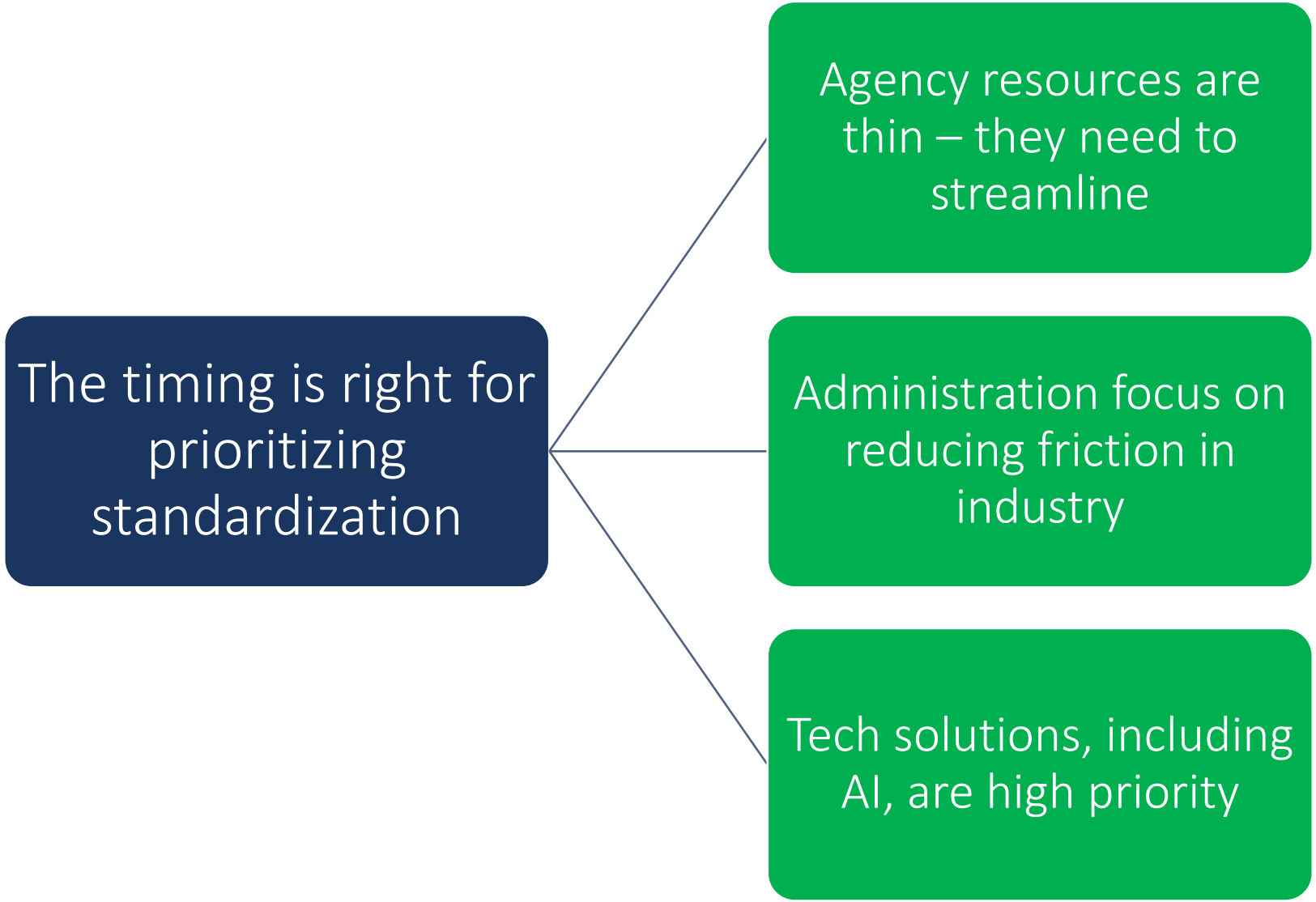
Standardize

Educate Agency and advocate for consistency

Innovate

Less iteration = more time for innovation

Challenge Creating Opportunity



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