Innovation x Access

3rd INTERNATIONAL WORKSHOP

Accessible Quality-Assured Diagnostic Tests for Public Health Programs

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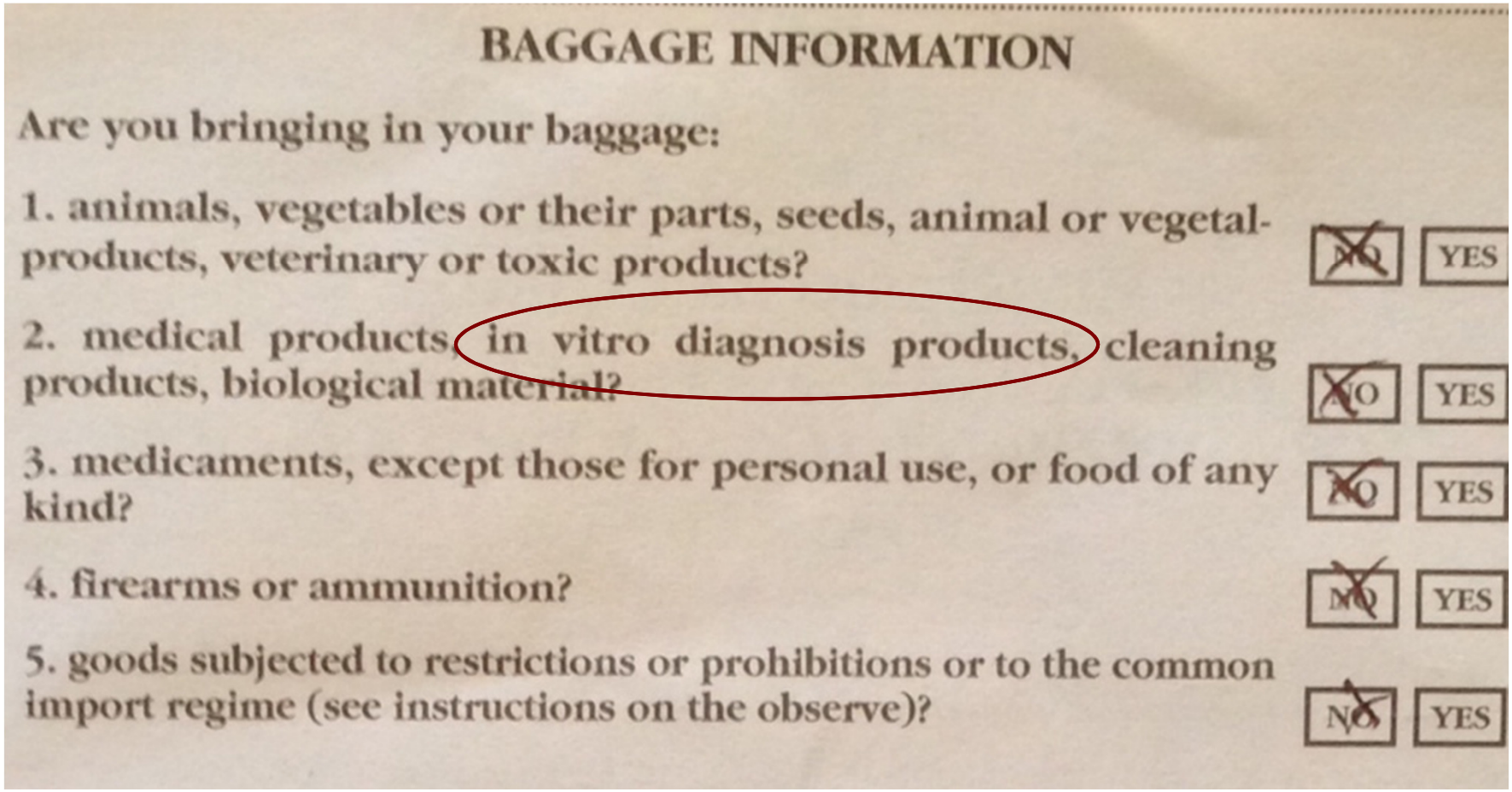
Evidence that Brazil Prioritizes IVDs



BAGGAGE INFORMATION

Are you bringing in your baggage:

1. animals, vegetables or their parts, seeds, animal or vegetal-products, veterinary or toxic products?	NO	YES
2. medical products, in vitro diagnosis products, cleaning products, biological material?	NO	YES
3. medicaments, except those for personal use, or food of any kind?	NO	YES
4. firearms or ammunition?	NO	YES
5. goods subjected to restrictions or prohibitions or to the common import regime (see instructions on the observe)?	NO	YES

Where we want to be…

- Have tests that are:

Reliable – always work

Accurate – provide a correct result

Robust – compatible with extreme working and storage conditions

REGULATION

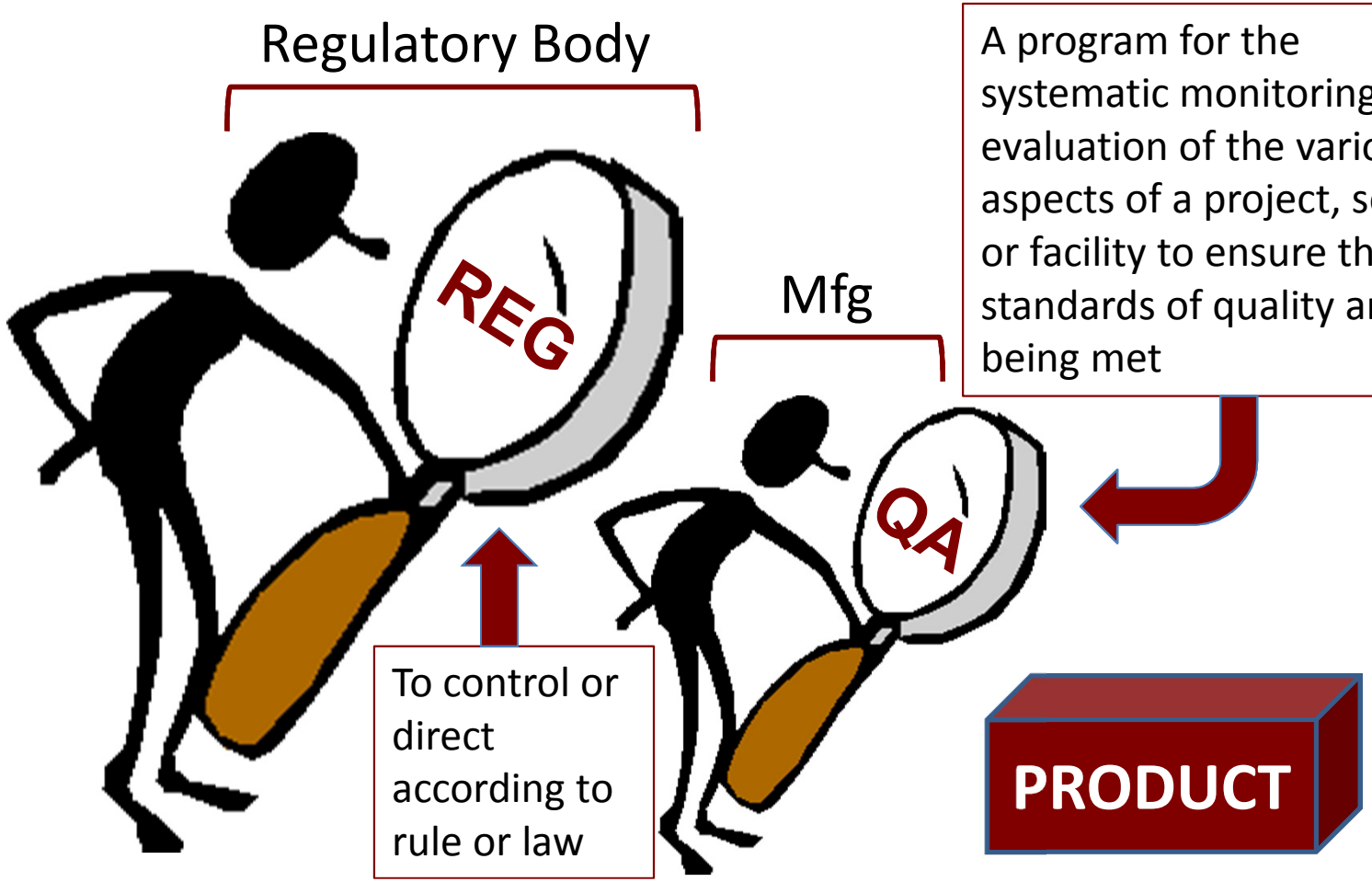
Affordable – to meet budget constraints

Available – in sufficient supply to meet demand

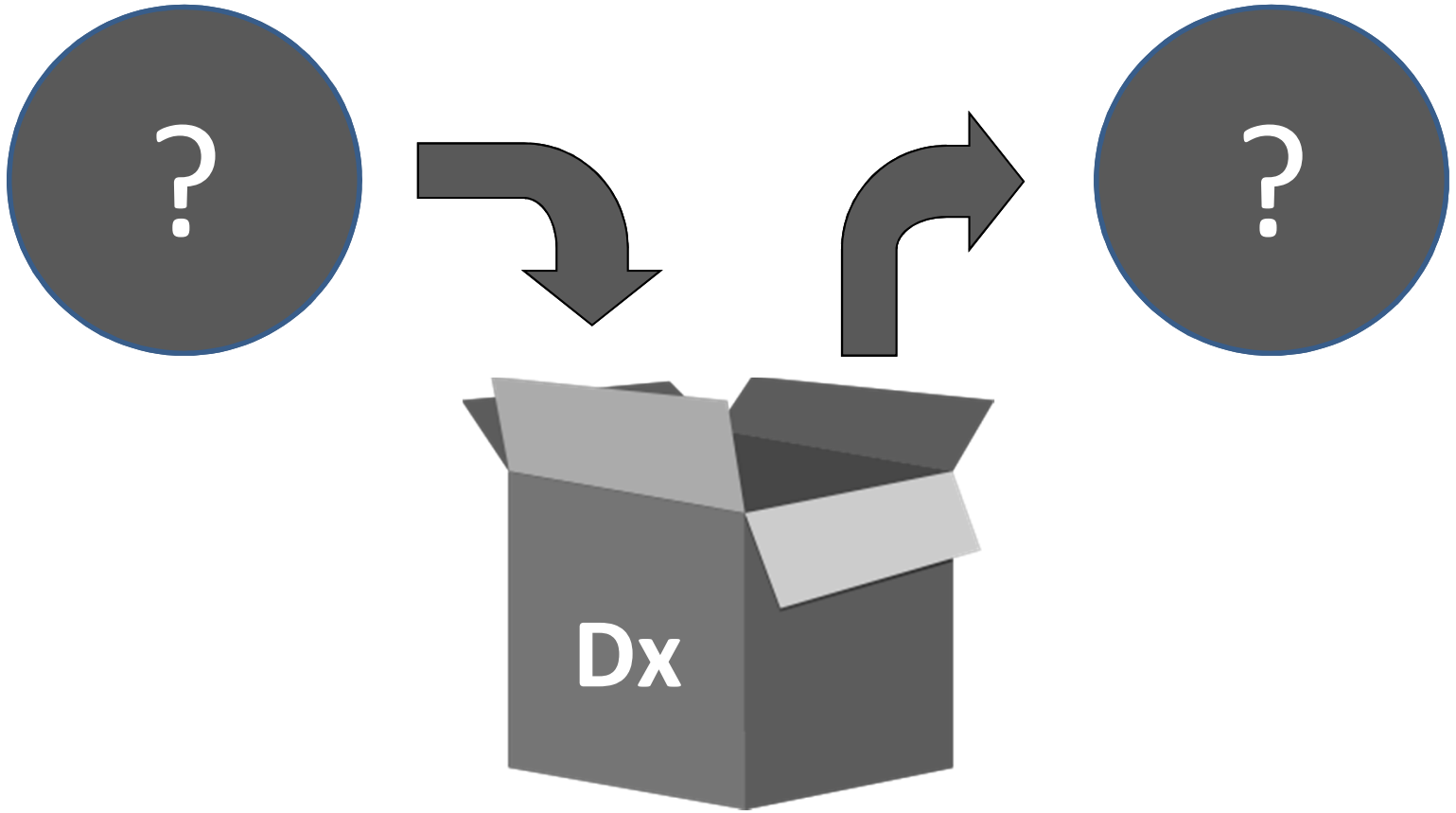
Compatible – appropriate for the population with which it will be used

ACCESS

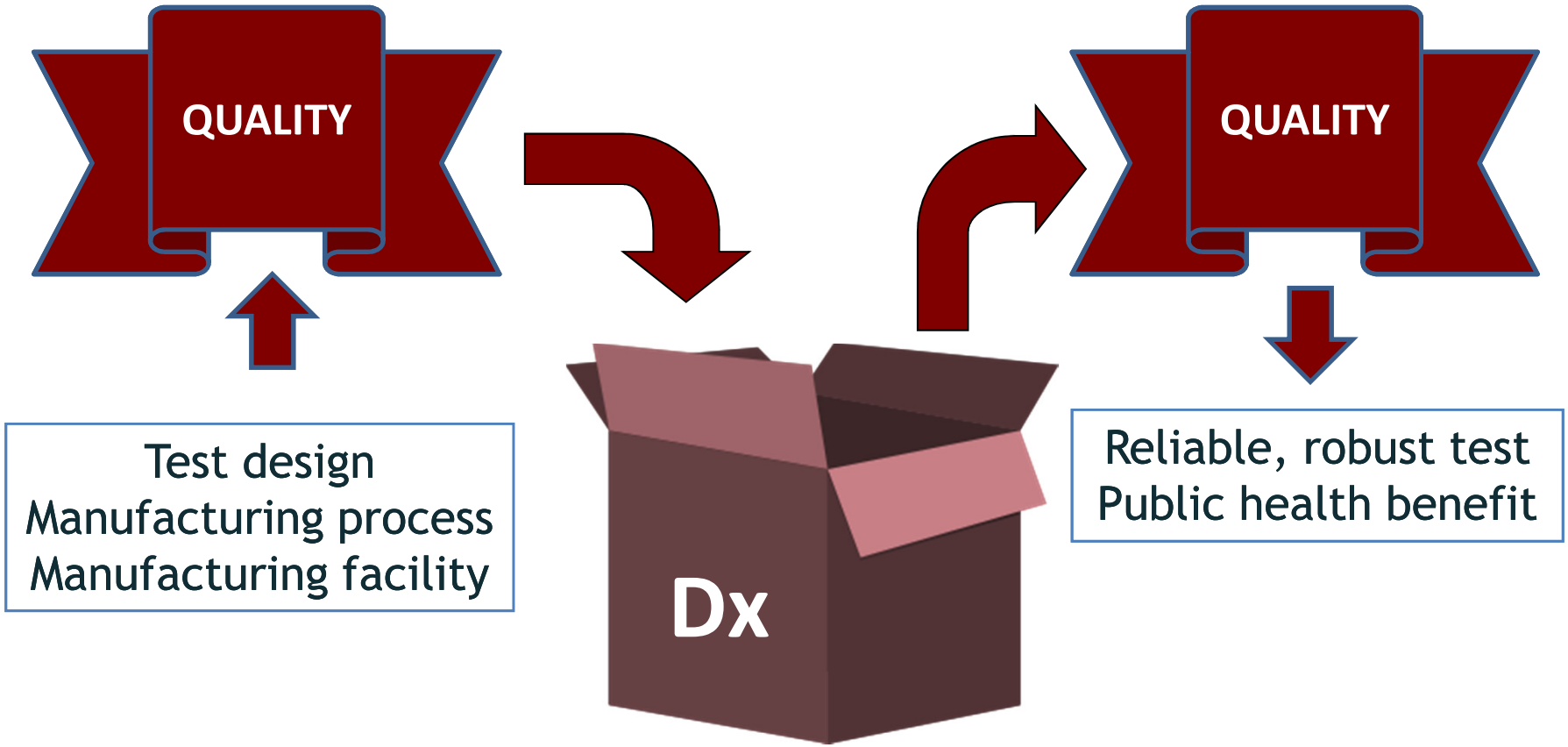
Regulation and Quality Assurance



Out of Control



In Control


QUALITY
QUALITY
Test design
Manufacturing process
Manufacturing facility
Dx
Reliable, robust test
Public health benefit

What is the purpose of regulation?

nsure that products are safe and effective for their intended use.

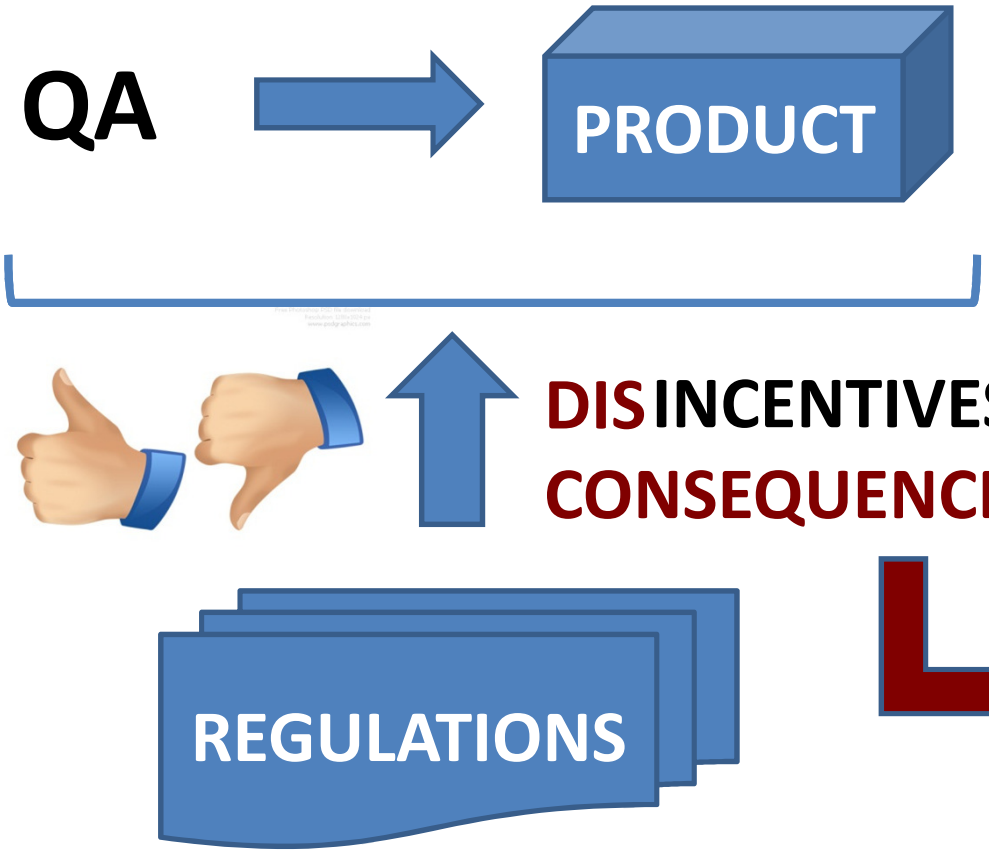
valuate evidence to support claims.

nforce the regulations.

Applying Regulations: Ensure and Evaluate

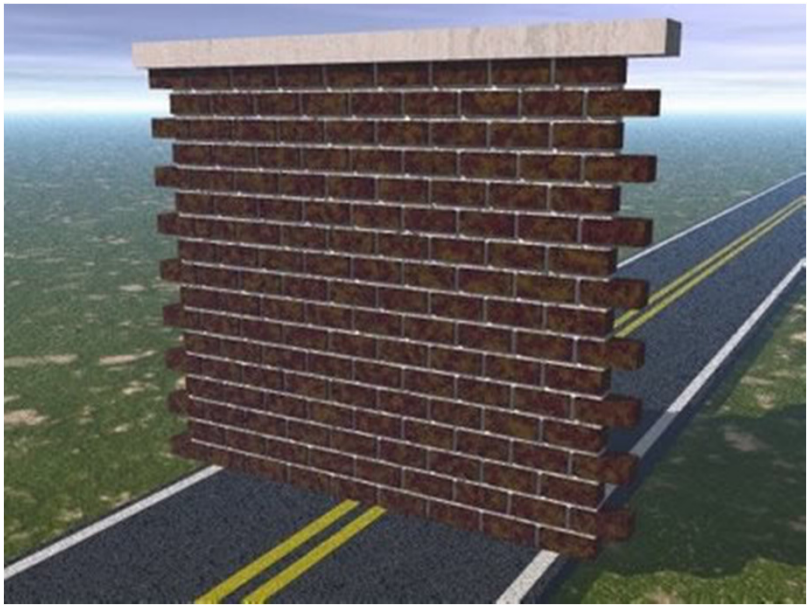
- Pre-market: Deciding whether to allow use of a product
  - Documentation review
  - Inspections
  - Additional studies?
- Post-market: Monitoring how well the product performs after approval
  - Active: Lot testing, sentinel sites, EQA
  - Passive: User reports

Applying Regulations: Enforce



- Consistent performance
- Trust in results
- Public health benefit
- Optimized use of resources

Perspectives on Regulation of IVDs



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Protect public health

Protect individual health

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Prevent access

Prevent innovation

Challenges

But consider short term savings vs. long-term costs when thinking about the cost of quality…

Overlooked Costs of Low Quality Tests

- Not treating infected individuals
  - Continued spread of infectious agents
  - Individual health impact
- Treating non-infected individuals
  - Wastes valuable resources
  - Contributes to resistance
  - Side effects of treatment for individuals
- Contributes to keeping high quality tests out of the market

CONSIDERATIONS FOR STREAMLINING THE IVD REGULATORY PROCESS

1. Consider building regional systems.

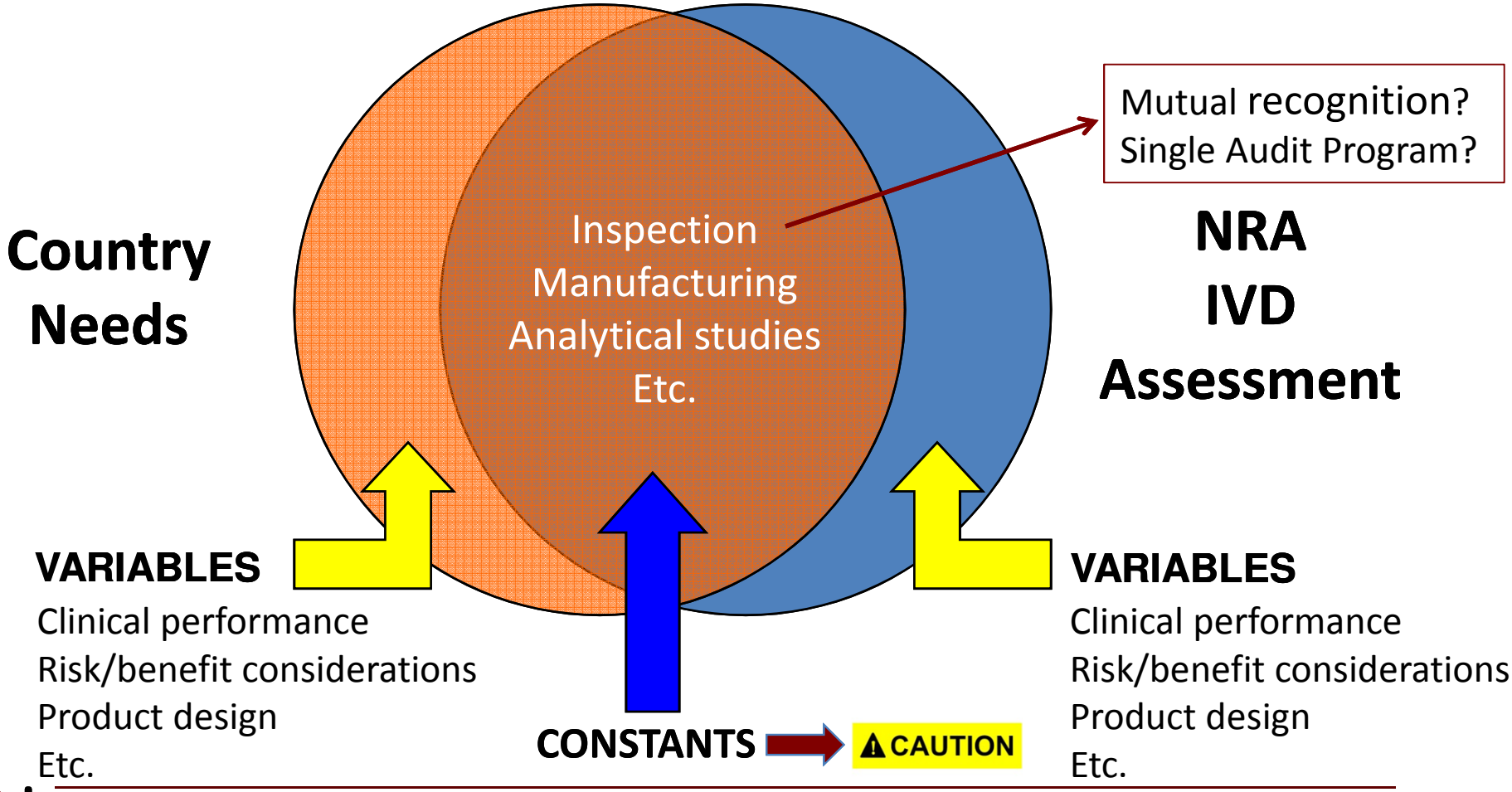
- Regulatory joining together to create "regulatory"
  - Makes process more efficient since if acceptable to region, then acceptable to individual member countries
    - Potential to streamline product introduction
  - Challenges in enforcement without legal backing
    - Consider alternative incentives/disincentives (economic?)

2. Leverage resources.

Don’t reinvent the wheel.

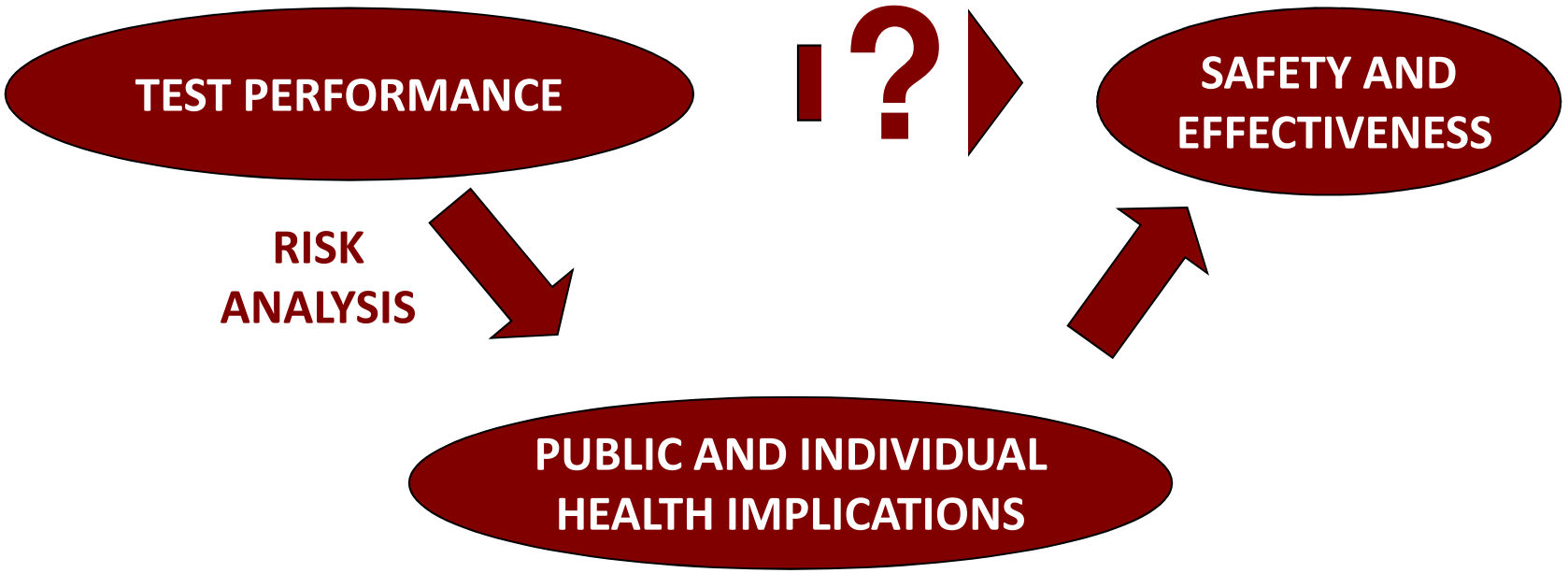
Don’t re-invent the parts of the wheel that don’t need re-inventing. Be aware of the limits.

Streamlining the Process: Products Approved by Another Body



3. Use a risk-based approach.

- Risk classification system to set priorities
- Risk assessment to make informed decisions



Example: FDA Approval of Over-the-Counter HIV Test

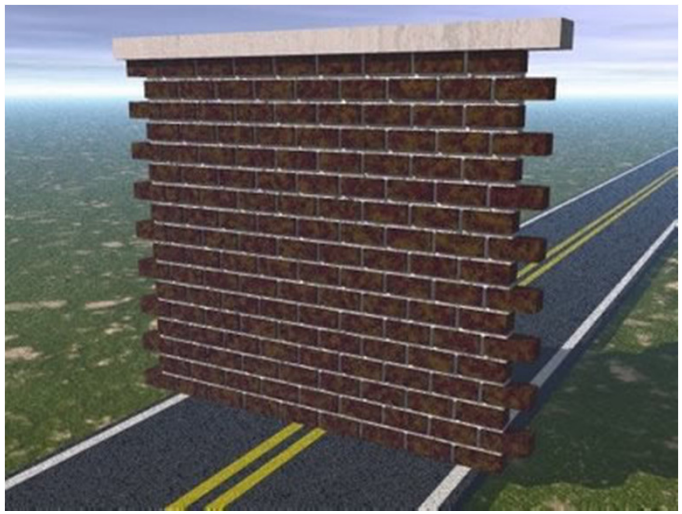
	Performance of the OraQuick® In-Home HIV Test Kit (2-sided 95% CI)	BPAC Minimum Recommended Performance
Specificity	99.98% (**99.90** – 100%)	**95%** (lower bound of the 95% CI)
Sensitivity	92.98% (**86.64** – 96.92%)	**95%** (lower bound of the 95% CI)

FDA Approach

- Based on a risk assessment model, FDA projected a net public health benefit to the OraQuick® In-Home HIV Test
  - Net increase in number of HIV infections newly identified in the first year
  - Net transmissions averted
- Individual risk remains in the form of increased numbers of false negative results
- Mitigate residual risk through labeling

ANOTHER PERPSECTIVE ON HOW REGULATION CAN “DRIVE” ACCESS AND INNOVATION WHILE MAINTAINING QUALITY

Evolution of a Regulatory System



Evolution of a Regulatory System

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Evolution of a Regulatory System

- Faster for all stakeholders
- Effective
- Takes advantage of advancing technology
- Less expensive (?)

Some Concluding Thoughts

- Regulatory systems (and “regulatory” systems) play a critical role in ensuring safety and efficacy and evolve
- Challenges to a regulatory system
  - Changes to a product
  - Regulatory versions
  - Monitoring performance: Post-market surveillance
  - Resources

But it won’t work…

…unless ALL stakeholders pull together…